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Local 322 of Southern New Jersey and the New Jersey Class

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
(*Camden Vicinage*)

UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS LOCAL 322 OF SOUTHERN NEW JERSEY, ***individually and on behalf of all others similarly situated,*** Plaintiff, v. **MALLINCKRODT ARD, LLC,** ***f/k/a Mallinckrodt ARD, Inc.;*** ***f/k/a* Questcor Pharmaceuticals, Inc.** **MALLINCKRODT PLC;** **CIGNA HOLDING COMPANY;** **CIGNA CORPORATION;** **EXPRESS SCRIPTS HOLDING COMPANY;** **EXPRESS SCRIPTS, INC.;** **CURASCRIPT, INC.;**	**C.A.No. 1:20-cv-00188-RBK-KMW**

CURASCRIPT SD; **PRIORITY HEALTHCARE CORP. AND PRIORITY HEALTHCARE DISTRIBUTION, INC.,** ***doing business as*** **CURASCRIPT SD AND CURASCRIPT SPECIALTY DISTRIBUTION SD,** ***respectively*****;** **ACCREDO HEALTH GROUP, INC.;** **UNITED BIOSOURCE CORPORATION,** ***now known as*** **UNITED BIOSOURCE LLC,** ***a wholly owned subsidiary of*** **UNITED BIOSOURCE HOLDINGS, INC.;** **LISA PRATTA** Defendants.	

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AMENDED CLASS ACTION COMPLAINT

Plaintiff, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey ("Plumbers Local 322", "Local 322" or "Plaintiff"), individually, and on behalf of other similarly situated current citizens and residents of New Jersey only, by and through its undersigned counsel, alleges as follows:

1. Plaintiff brings this action on behalf of itself and a New Jersey class of all similarly situated third party payors ("TPPs") and their beneficiaries, who, like Local 322, paid for the cost of Acthar prescribed in, sold in, shipped to and administered by self-injection in the State of New Jersey, to challenge the unjust, unfair and deceptive marketing and sales scheme and conspiracy, and the anti-competitive conduct, by Defendants, Mallinckrodt ARD Inc., formally known as Questor Pharmaceuticals, Inc. ("Questor") and its parent company, Mallinckrodt plc (collectively "Mallinckrodt"), as well as Mallinckrodt's exclusive agent for the delivery of its principal product, Cigna Holding Company and Cigna Corporation, by and through their wholly-owned subsidiaries, Express Scripts Holding Company ("ESHC") and Express Scripts, Inc. ("ESI")(collectively "Express Scripts"), CuraScript, Inc., doing business as CuraScript SD, formerly known as CuraScript Pharmacy, Inc., ("CuraScript"), Priority Healthcare Corp. and Priority Healthcare Distribution Inc. ("Priority") also doing business as CuraScript SD (collectively, "CuraScript SD"), Accredo Health Group, Inc. ("Accredo"), and United BioSource Corporation n/k/a United BioSource LLC ("UBC")(collectively referred to as the "Cigna"). Plaintiff and the Class also sue Lisa Pratta, a former sales specialist for Mallinckrodt in New Jersey and now *qui tam* relator against the company, for her direct role in the unlawful conduct alleged herein prior to the time she decided to cease the unlawful conduct and sue her former employer.

2. The Class includes only current citizens and residents of New Jersey who purchased Acthar in New Jersey. Because only Defendants know the names and addresses of these Class members, by virtue of the operation of the ASAP program and direct communications with such TPPs and their beneficiaries as described herein, discovery of Defendants will be required before the identities of all New Jersey Class members may be ascertained by this Court. However, to the extent any language in this Complaint may be construed as either attempting to expand the scope Class beyond current New Jersey citizens and residents, or to expand the Class claims beyond claims under New Jersey law, such construction is hereby expressly and unequivocally rejected and disavowed. Plaintiff seeks to represent only current New Jersey citizens and residents who purchased Acthar in New Jersey and suffered economic harm as a result of Defendants' conduct in violation of New Jersey law.

3. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar Gel, NDC Nos. 63004-8710-01 and 63004-7731-01 (**"Acthar"**). Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is the sole provider of Acthar in the U.S.

4. Mallinckrodt acquired Acthar in July 2001, when Questcor purchased Acthar from Aventis Pharmaceutical Products Inc. for $100,000. At the time, the drug cost around $40.00. But in 2007, Mallinckrodt decided to raise the price 100,000 percent, to over $29,000. It could only get away with such an unconscionable price increase by conspiring with others, most notably the largest pharmacy benefits manager in America, Cigna's Express Scripts.

5. Acthar is a "specialty pharmaceutical". Unlike most prescription drugs, it is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies. Instead, it is distributed only through "specialty pharmacy distributors" (**"SPDs"**) and "specialty pharmacy providers" (**"SPPs"**).

6. While there are dozens of SPDs and SPPs in America, one of the largest SPDs is CuraScript, Inc., doing business as CuraScript SD, and Priority Healthcare Corp, also doing business as CuraScript SD (collectively, "**CuraScript**"). One of the largest SPPs is Accredo Health Group, Inc. ("**Accredo**"). Express Scripts, Inc. has owned both CuraScript and Accredo since 2004. Express Scripts also owned UBC, and its predecessor entity HealthBridge, from 2007 through the end of 2017.

7. In 2007, Mallinckrodt decided to embark on a self-described "new strategy" with respect to the distribution, pricing, marketing and sales of Acthar. The goal was to raise the price of Acthar from $1,650 to over $29,000, so that it [and others] could realize unlawful profits from the sale of a 65-year old medication.

8. The masterminds of the new strategy appear to have been three main people at Mallinckrodt: (1) Gregg LaPointe, who was placed on the Questcor's Board of Directors in July 2005 by Questcor's largest investor, Sigma-Tau; (2) Steve Cartt, a 14-year veteran of Alza Corporation (a wholly-owned subsidiary of New Jersey's Johnson & Johnson), who was hired as Questcor's Executive Vice-President of Commercial Development in March 2005, and (3) another Board member, Don Bailey, who was elevated to Interim CEO in May 2007 after the new strategy was adopted, but previously joined the Board in 2006. On information and belief, these three pushed the new strategy through, over the objections of the existing Questcor CEO and several other Board members and executives who all left the company after the strategy was adopted.

9. The new strategy had three essential components to it. These three components comprise the schemes that underscore the antitrust, RICO enterprises and unfair and deceptive acts and practices at issue in this case.

10. **First**, Mallinckrodt changed the way it distributed and sold Acthar (the "**Distribution Scheme**"). It limited the distribution of Acthar from multiple distribution outlets to just one, CuraScript, and engaged UBC to act as its exclusive "HUB" of operations controlling both the distribution and reimbursement of Acthar directly with patients and TPPs. (CuraScript and UBC were both subsidiaries of Express Scripts.) Mallinckrodt created this exclusive distribution arrangement to limit and control distribution and output of Acthar, and to raise the prices of Acthar to unconscionable levels. Mallinckrodt and UBC created the Acthar Support and Access Program ("ASAP") described below as the vehicle to effectuate their Distribution Scheme.

11. While this conduct constitutes antitrust, and is the subject of a separate federal class action lawsuit pending in Rockford, Illinois[1], it is also the subject of separate *qui tam* lawsuits brought in Philadelphia by former employees of Mallinckrodt, in which the federal government has intervened. *See U.S. ex. Rel. Charles Strunck and Lisa Pratta v. Mallinckrodt ARD, Inc., et al.* 2:12-cv-00175-BMS (E.D.Pa.) at Document No. 40 ("*Strunck & Pratta Complaint*"); *U.S. ex. Rel. Scott Clark v. Questcor Pharmaceuticals, Inc.*, 2:13-cv-01776-BMS (E.D.Pa.) at Document 1 ("*Clark Complaint*"). The facts alleged in the *Strunck & Pratta Complaint* and the *Clark Complaint* are incorporated by reference thereto to bolster the facts alleged by Plumbers Local 322 in this case.

12. Plumbers Local 322 brings no overlapping claims against Defendantsin this lawsuit for any alleged federal antitrust or RICO violations, or any other federal claim. Instead, it sues on behalf of itself and all similarly situated TPPs and beneficiaries who purchased Acthar for New Jersey consumer fraud, RICO and antitrust violations, and other New Jersey common

[1] *See City of Rockford v. Mallinckrodt ARD, Inc., et. al.*, Case No. 17-cv-50107 (N.D.Ill.) (hereinafter the "***Rockford* case**").

law claims arising out of the unique distribution, pricing, marketing and sales schemes alleged herein. Some of the details of the conduct underlying these claims were only first revealed to Plaintiff and the Class in April 2019 when the *Strunck and Pratta Complaint* was unsealed by the federal District Court in Philadelphia.

13. **Second**, throughout the relevant time period, since August 2007 through the present, Mallinckrodt has willfully manipulated and inflated the prices paid by TPPs for Acthar, causing TPPs like Local 322 to substantially overpay for a drug with very limited uses and benefits and an unknown method of action (the "**Pricing Scheme**"). Specifically, after limiting Acthar distribution by the Distribution Scheme, in August 2007, Mallinckrodt agreed with CuraScript and UBC to raise the average wholesale prices ("**AWPs**") paid for Acthar by TPPs like Local 322 from $2,062.79 per vial to $29,086.25, a more than 1,300% increase in the cost of Acthar in the span of one month. Such a price increase is both unprecedented and unconscionable, especially for a more than 65-year old drug. Mallinckrodt has continued to raise the AWPs for Acthar each year, sometimes by double-digit percentages, such that now a drug that once cost $40.00 costs patients and TPPs, like Plumbers Local 322, over $43,000.00. The only way Mallinckrodt has been able to get TPPs to pay such high prices for Acthar was through the fraudulent schemes alleged herein. But for such schemes, TPPs like Plumbers Local 322 would not have paid what they did for Acthar.

14. In conjunction with limiting Acthar distribution and raising the prices for Acthar in 2007, Mallinckrodt embarked on a marketing scheme designed to incentivize sales of Acthar at the new high prices. Patients and TPPs, like Plumbers Local 322, had no choice but to pay the high prices charged by Mallinckrodt and Cigna's UBC subsidiary, Mallinckrodt's exclusive agent and "HUB".

15. **Third**, Mallinckrodt devised a marketing and sales scheme designed to ensure that Acthar was reimbursed by TPPs at the new, inflated AWPs, without substantial backlash from patients and payors (the "**Marketing Scheme**"). Fearing an uproar of complaints from patients, patient support groups, private TPPs and the federal government for their unjustified distribution limitations and price increases, and in order to circumvent TPP cost containment mechanisms for high-priced specialty drugs, Mallinckrodt devised a multi-faceted scheme of antitrust and consumer fraud, and a RICO enterprise to bribe doctors in order to induce them to prescribe Acthar over other available treatments. The scheme involved an enterprise cultivating key opinion leaders (or "KOLs") in New Jersey to serve as the company's "spokes-doctors" in promoting prescriptions of Acthar for unapproved uses and doses in the State. The scheme also sought to remove patient complaints about high co-pays on Acthar by funneling tens of millions of dollars to UBC to run a so-called "patient assistance program" or "PAP" designed to ensure that private TPPs paid the bulk of the costs of Acthar.

16. On April 30, 2019, it was revealed publically for the first time by CNN[2] that two whistleblowers, both former pharmaceutical sales representatives for Mallinckrodt, had sued the company years before for a "multi-tiered strategy" to boost sales by bribing doctors to prescribe the high-priced Acthar to their patients. As described more fully in the *Strunck & Pratta Complaint*, Mallinckrodt's scheme involved "using valuable incentives, rewards and other forms of renumeration to induce health care providers to promote and prescribe H.P. Acthar in lieu of less expensive therapies that are equally more effective…". *Strunck & Pratta* Cmplt. at ¶ 3(i). According to Strunck and Pratta, there is a pervasive culture at Mallinckrodt designed to sell Acthar at all costs.

[2] https://www.cnn.com/2019/04/30/health/mallinckrodt-whistleblower-lawsuit-acthar/index.html

17. Separately, a different whistleblower sued Mallinckrodt in this Court on April 4, 2013, alleging a different aspect of Mallinckrodt's scheme to sell Acthar at high prices. In a case unsealed as part of the government's filing of a consolidated, amended pleading, former employee Scott Clark alleges that "Mallinckrodt designed supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations', knowing its money would be used on Acthar copays to the exclusion of other drugs." *See* United States' Complaint in Intervention, Dkt No. 2:13-cv-01776-BMS (E.D.Pa.) (BMS) at Document No. 57 ("***U.S. Complaint***") at ¶ 5.[3] Such conduct is unlawful.

18. As the federal government alleged:

> "Mallinckrodt knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations in multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt intended to overcome this difficulty and did so by making the drug 'free' to patients by subsidizing their Medicare [and private] copayments. By doing so, Mallinckrodt could maintain the high price of Acthar to maximize its own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it."

Id. at ¶ 4 (brackets added).

19. Accordingly, in conjunction with limiting Acthar distribution and raising the prices for Acthar in 2007, as part of the Distribution and Pricing Schemes, Mallinckrodt also embarked on a Marketing Scheme designed to incentivize sales of Acthar at the new high prices. Patients and TPPs, like Plumbers Local 322, had no choice but to pay the high prices charged by Mallinckrodt through UBC, Mallinckrodt's exclusive agent and "HUB".

20. Mallinckrodt vastly expanded its direct-to-consumer selling of Acthar by

[3] Plaintiff hereby asks this Court to take judicial notice of the federal government's pleading, which was the product of a seven-year investigation into the claims by Relators Pratta, Strunck and Clark.

expanding its sales force, including creating a team of "medical science liaisons" or "MSLs". The MSLs were highly trained specialists in the Acthar treatments who worked with other Mallinckrodt sales representatives to create a network of KOLs. These KOLs were leading specialists in their respective medical fields whom Mallinckrodt identified as being potentially influential on other doctors. These KOLs were paid handsomely to join with Mallinckrodt's MSLs and sales representatives as "spokes-doctors", promoting Acthar to other medical providers and delivering Mallinckrodt's false, misleading and deceptive promotional messages about the mode of action, safety, efficacy and value of Acthar in relation to other cheaper, safer, and equally or more effective treatments. As a result, thousands of new patients have been prescribed Acthar for unapproved uses and doses in the treatment of diseases in neurology, nephrology and rheumatology, among others. And TPPs have been forced to pay the exorbitant prices charged by Defendants.

21. Plumbers Local 322, along with other TPPs who have sued in state courts around the country,[4] and the Class of TPPs and their beneficiaries who purchased Acthar in New Jersey, were harmed by Mallinckrodt's conduct. Specifically, Plumbers Local 322 has paid for Acthar at the inflated prices charged by Defendants as a result of the Distribution, Pricing, and Marketing Schemes alleged. On one such occasion, Plumbers Local 322 spent $26,100.28 for just 1 administration of Acthar given to 1 patient.

22. Plumbers Local 322 brings this lawsuit on behalf of itself and a Class of all similarly-situated TPPs and their beneficiaries who paid for Acthar in New Jersey at prices based

[4] One such TPP is the International Union of Operating Engineers Local 542 ("IUOE Local 542") based in Fort Washington, Pennsylvania. IUOE Local 542 sued Mallinckrodt and UBC in the Court of Common Pleas for Montgomery County, Pennsylvania in May 2018. That case is proceeding through discovery. Another TPP is Steamfitters Local Union No. 420 **(**"Local 420"). Local 420 sued in the Eastern District of Pennsylvania as a related case to the

on the inflated AWP prices set by Mallinckrodt during the relevant time period between August 2007 and the present. Plaintiff seeks declaratory and injunctive relief in this Court on behalf of a New Jersey Class of TPPs and their beneficiaries, in order to have the conduct of Mallinckrodt declared unlawful and enjoined. Plaintiff also seeks to recover money damages for overpayments based on inflated AWP prices for Acthar, pursuant to New Jersey antitrust and RICO and the New Jersey consumer Fraud Act, as well as the New Jersey common law. Finally, Plaintiff seeks punitive damages for Mallinckrodt's willful, outrageous and reckless conduct.

JURISDICTION AND VENUE

23. Plumbers Local 322 brings this action pursuant to statutory laws of New Jersey, as well as New Jersey common law. No aspect of the claims asserted in this Complaint is brought pursuant to any federal law, including, but not limited to federal RICO, the federal Sherman Act, or the Clayton Act, and thus no federal question is raised by any of Plaintiff's claims. To the extent any of Plaintiff's claims or factual allegations herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by Plaintiff. Moreover, to the extent any of Plaintiff's claims or factual allegations herein are urged by Mallinckrodt to have stated any claim under federal law, Plaintiff expressly disavows such claims or allegations and reserves the right to modify this Complaint to conform its claims.

24. This Court has personal jurisdiction over Plaintiff because it resides in New Jersey, and because its members and beneficiaries all reside within, and have purchased, used and reimbursed the costs of Acthar, within the State of New Jersey.

25. This Court has jurisdiction over Mallinckrodt because its corporate headquarters is in Bedminster, New Jersey and it conducts substantial business in this State, has had

systematic and continuous contacts with this State, and has officers, employees, agents and representatives that can be found in this State. Mallinckrodt also has a business location in Hampton, New Jersey. The Court also has jurisdiction over Ms. Pratta because she lives in New Jersey. Finally, the Court has jurisdiction over Cigna/Express Scripts because they have physical offices and business locations in New Jersey.

26. Venue is proper in this Court because Plaintiff is situated in Camden County, and Defendants transact business in this County. Venue is also proper because a substantial part of the events giving rise to the Plaintiff's claims occurred in this County. Defendants engaged in substantial conduct relevant to the Plaintiff's claims and caused harm to Plaintiff in Camden County, New Jersey. Relator Pratta also engaged in substantial conduct in this County relating to the claims of Plaintiff and the Class because Pratta's sales territory was southern New Jersey, all part of the Camden vicinage of this Court.

THE PARTIES

PLAINTIFF

27. Plumbers Local 322 is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. Plumbers Local 322 resides at 534 South State Highway 73, Winslow, New Jersey 08095, which is situated in Camden County, New Jersey.

28. Plumbers Local 322 has represented the interests of working men and women skilled as plumbers, pipefitters, and heating, ventilation and air conditioning (HVAC) service technicians in Southern New Jersey since 1912. Local 322 works in all sectors of the piping industry of Southern New Jersey including power generating facilities, petro chemical industry facilities, educational facilities, Southern New Jersey health care facilities, the Atlantic City Casino and Tourism Industry, shopping centers, state and federal institutional facilities, the

HVAC Service Industry, housing developments throughout Southern New Jersey, maintenance for the Convention Centers, the Aquarium, and the USS New Jersey Battleship, and the redevelopment of the Atlantic City Airport.

29. Local 322 paid for Acthar distributed directly from Mallinckrodt's authorized agent, Cigna/Express Scripts, to Local 322's beneficiary, and sold through Defendant Pratta in whose sales territory Plaintiff and its beneficiary reside. Local 322, which pays the health care benefits of its members, including specialty pharmacy drugs, then paid $26,100.28 directly to Cigna/Express Scripts, as agent for Mallinckrodt. The amount paid was based on the inflated AWP for Acthar, as set by Mallinckrodt with Cigna/Express Scripts. The monies paid by Local 322 were directly transferred by Cigna/Express Scripts to Mallinckrodt, after Cigna/Express Scripts deducted their agreed-upon share of the revenues pursuant to express agreements between the companies.

DEFENDANTS

30. Defendant Mallinckrodt ARD LLC ("Mallinckrodt") has its principal place of business at 1425 U.S. Route 206, Bedminster, New Jersey 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and before that was named Questcor Pharmaceuticals, Inc. ("Questcor").

31. Mallinckrodt ARD LLC is an indirect wholly-owned subsidiary of Mallinckrodt plc, an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom.

32. Defendant Mallinckrodt plc ("Mallinckrodt plc") is an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, the Causeway, Staines-upon-Thames,

Surrey, TW18 3 AG.

33. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014 for approximately $5.9 billion.

34. Following the merger, Questcor continued to market and sell Acthar, until changing its name to Mallinckrodt ARD Inc. on July 27, 2015.

35. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and continues to market Acthar under that name today.

36. Mallinckrodt plc and Mallinckrodt ARD are collectively referred to as "Mallinckrodt".

37. On August 14, 2014, Mallinckrodt acquired Questcor Pharmaceuticals, Inc. ("Questcor") for $5.9 billion, after Questcor had paid only $100,000 for Questcor's lone product Acthar 13 years earlier. Mallinckrodt now charges patients over $200,000 for a course of treatment of Acthar [5 vials at more than $40,000 per vial]. This is twice what Questcor paid to acquire the product in 2001.

38. Following the acquisition, Questcor became a wholly-owned subsidiary of Mallinckrodt and its name was changed to Mallinckrodt ARD Inc.

39. At the time of the Mallinckrodt acquisition of Questcor in 2014, Mallinckrodt ARD's only product sold in the United States was Acthar. Since the acquisition, Mallinckrodt has continued to manufacture, distribute, market and sell Acthar directly to patients, exclusively through Express Scripts, by a program known as the "Acthar Support and Access Program" (***"ASAP"***) described more fully below.

40. Defendants Cigna Corporation (hereinafter ***"Cigna Corp."***) and Cigna Holding Company are Delaware corporations with their corporate offices and principle place of business located at 900 Cottage Grove Road, Bloomfield, Connecticut.

41. Cigna claims to "deliver" choice, predictability, affordability and quality care through integrated capabilities and connected, personalized solutions that advance whole person health.

42. Express Scripts, Inc. (***"ESI"***) and ESHC are Delaware corporations with their principle executive offices located at 1 Express Way, Saint Louis, Missouri 63121 and Century Center Drive, Memphis, Tennessee (collectively, ***"Express Scripts"***). Cigna successfully completed its acquisition of Express Scripts effective December 20, 2018 and now the companies are one. Cigna now refers to the merged entity as "New Cigna".

43. The merger/combination of Cigna with Express Scripts, as described by Cigna,[5] integrates two complementary health care service companies, each with industry-leading cost trend capabilities that together are positioned to deliver better care, expanded choice and drive down health care costs. Contrary to its public statements, Cigna has done nothing to drive down the costs of Acthar. Instead, Cigna continues to conspire and agree with Mallinckrodt to maintain the high Acthar prices mutually set by the Defendants since 2007. Cigna continues the unlawful marketing, promotion, distribution, pricing and sales practices described herein.

44. Priority Healthcare Corp. and Priority Healthcare Distribution Inc. (***"Priority"***) d/b/a CuraScript SD (collectively, ***"CuraScript SD"***), are wholly-owned subsidiaries of Cigna/Express Scripts. Priority/CuraScript SD has maintained corporate offices at 1680 Century

[5] https://www.cigna.com/newsroom/news-releases/2018/cigna-completes-combination-with-express-scripts-establishing-a-blueprint-to-transform-the-health-care-system

Center Parkway, Memphis, Tennessee 38134-8827.

45. CuraScript, Inc., d/b/a CuraScript SD, f/k/a CuraScript Pharmacy, Inc., is a wholly-owned subsidiary of Cigna/Express Scripts. ESHC acquired CuraScript in January 2004. Its operation was expanded when ESHC acquired Priority in October 2005 and combined it with CuraScript. The combined Priority and CuraScript SD (collectively ***"CuraScript"***) became one of the nation's largest specialty pharmacy and distribution companies with more than $3 billion in annual revenue.

46. CuraScript is an Indiana corporation with corporate offices located at 255 Technology Park, Lake Mary, Florida 32746. This is the same Florida address patients are required to mail any revocation of the broad authorization granted by patients to Mallinckrodt and Express Scripts via the Acthar Start Form (Exhibit "A" hereto). CuraScript has been Mallinckrodt's exclusive specialty pharmacy distributor for Acthar since 2007.

47. Significantly, Mallinckrodt chose to end Cigna/Express Scripts' exclusive distribution relationship in September 2017 only after the companies were sued for antitrust in 2017 by the City of Rockford, Illinois, in wake of the Mallinckrodt's settlement with the FTC of antitrust violations. Yet, since 2017, Cigna has done nothing to reverse the harmful effects of Express Scripts' unlawful conduct described herein, or to end the unlawful acts or practices described herein, which continue to expose Plaintiff to future harm.

48. CuraScript directly delivered the Acthar paid for by Plumbers Local 40 to its covered beneficiaries.

49. Accredo Health Group, Inc. (***"Accredo"***) is a wholly-owned subsidiary of Cigna/Express Scripts. Accredo became a wholly-owned indirect subsidiary of Medco Health Solutions, Inc. (***"Medco"***) on August 18, 2005, months before Express Scripts acquired Priority,

and then became part of Express Scripts when Express Scripts acquired Medco in 2012. At that time, Medco became a wholly owned subsidiary of ESHC.

50. Accredo is a Delaware corporation with its corporate headquarters at 1640 Century Center Parkway, Memphis, Tennessee 38134 Accredo also has operations in Warrendale, Pennsylvania, Corona, California, Greensboro, North Carolina, Orlando, Florida, and Indianapolis, Indiana.

51. Accredo was the specialty pharmacy that reviewed approved all the administrations of Acthar paid for by Plumbers Local 40 at the inflated prices described herein.

52. United BioSource Corporation n/k/a United BioSource LLC (***"UBC"***) is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422 and a business location at 1670 Century Center Drive, Memphis, Tennessee. UBC was a wholly-owned subsidiary of Cigna/Express Scripts from 2012, when it was acquired by Express Scripts as part of the Medco merger, until November 2017, when Express Scripts announced that it sold UBC to Avista Capital Partners, a private equity firm.

53. UBC is a wholly owned subsidiary of United BioSource Holdings, Inc., the interests of which are held by and through various privately held intermediary entities, which are ultimately owned by private investment funds sponsored by and/or affiliated with Avista Capital Partners and as-yet-unknown individuals associated with Avista Capital Partners.

54. UBC is described as Mallinckrodt's "agent" on the Acthar Start Form (Exhibit "A" hereto) which Mallinckrodt employs exclusively to operate the ASAP program and to manage the exclusive distribution, sales and reimbursement of Acthar by Cigna's 3 operating arms, CuraScript, Accredo and Express Scripts.

55. UBC provides customer support and reimbursement support for Acthar as the

"HUB" of Express Scripts' three operating arms, CuraScript (providing specialty distribution services), Accredo (providing specialty pharmacy services) and Express Scripts (providing pharmacy benefit management services).

56. UBC received and handled the ASAP forms filled out by the Plumbers Local 322 beneficiary and their provider for the Acthar paid for by Plumbers Local 40.

57. As stated above, Cigna, ESI, ESHC, CuraScript, Accredo and UBC are all part of Cigna, and are collectively referred to herein as "Cigna".

58. Mallinckrodt and Cigna are collectively referred to herein as "Defendants", as appropriate.

59. Lisa Pratta is an individual and resident of New Jersey, and worked in a southern New Jersey sales territory, as defined by Questcor and Mallinckrodt, as a sales representative for Questcor and Mallinckrodt until she was forced to leave the company in 2017 when her purported "whistleblower" status against the company was revealed in court.

60. The corporate parties' acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

FACTUAL BACKGROUND

61. "I have a Cadillac in my refrigerator." That is how one Acthar patient named Sharon Keller described an unused 5-ml vial of the medication sitting in her kitchen refrigerator.

62. The tale of how a 65-year-old brand medication could rise in price from $40 per vial in 2001 to $40,840.80 per vial by 2015, and over $45,000 today, raising the value of the brand from $100,000 to $5.9 billion, is a story of perhaps the most egregious fraud and

conspiracy by a prescription drug company and a PBM in United States history.

A. ACTHAR DEVELOPMENT AND LIMITED APPROVAL BY THE FDA

63. Acthar was approved by the FDA on April 29, 1952 for over 50 conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, as discussed below, with additional evidence-based requirements for prescription drugs, the list was winnowed by the FDA to the fewer, present-day 19 indications.

64. Acthar is adrenocorticotropic hormone ("ACTH"), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed.

65. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co*., 274 F.2d 143, 145-46 (7th Cir. 1960):

> In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.
>
> The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTsH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

66. In layman's terms, ACTH is a hormone released by the brain that triggers the adrenal glands to make cortisol, which is the body's equivalent of prednisone, a steroid. ACTH

works by inducing a patient's adrenal glands to release cortisol, thereby replicating the effect of taking prednisone. Because of this, ACTH has risks and benefits similar to those of prednisone.

The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

67. Under FDCA 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

68. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(l)(A).

69. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. 21 U.S.C. §321. The law requires that "adequate and well controlled investigations" be used to demonstrate a drug's safety and effectiveness. 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. 37 Fed. Reg. 16,503 (1972). They are "unapproved" uses.

70. The standards that govern the FDA safety and effectiveness requirements are

contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. 21 C.F.R. § 314.26.

71. The FDA also requires the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. In order to address this requirement, the FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 Guidance to the Industry, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products, May 1998. *See also, Final Decision on Benylin*, 44 FR 51512, 518 (Aug. 31, 1979).

72. The FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. See S. Rep. No. 1744, Part 2, 87th Cong.2d Sess. 6 (1962).

73. In Section 115(a) of the Medicare Modernization Act, Congress amended section 505(d) of the Act to make it clear that the FDA may consider "data from one adequate and well-

controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if the FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the FDA's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

74. Cases in which the FDA has approved a drug on the basis of one clinical trial plus, confirmatory evidence are rare. They include instances of large, independently conducted multi-center trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

75. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. 21 C.F.R. § 201.57(3).

FDA Regulations Prohibit Off Label Marketing Through False and Misleading Statements About a Drug's Use or Benefits.

76. FDA regulations restrict how drug companies may market and promote approved drugs. See 21 U.S.C. §§ 331, 852; 21 C.F.R. § 314.81. Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C.§§ 331; 352. Illegal "misbranding" can result in criminal penalties. 21 U.S.C. § 333.

77. Drug companies such as Mallinckrodt must submit specimens of mailing pieces and any other labeling or advertising devised or used for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or "advertisement" for the product, which are also subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and m line with any written communications being submitted to FDA.

78. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false, deceptive or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

79. A drug company that wishes to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical

trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA") 21 U.S.C.§§ 360aaa(b), (c); *see also* 21 C.F.R.§ 814.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301, *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

80. The term "off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, e.g., treating a child when the drug is approved to treat adults.

81. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians are supposed to depend on the patient-specific evidence they have available to them. This should include the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on or off-label use, physicians also sometimes rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Regrettably, much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education ("CME") courses and speaker programs, and drug company sponsored clinical trials.

82. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

83. Any drug company's speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below. While a drug company may be entitled to certain First Amendment protection for truthful speech, see U.S. v. Caronia, 703 F.3d 149 (2d. Cir. 2012), off-label promotion that is false or misleading is not entitled to First Amendment protection. Caronia, 703 F.3d at 166 n. 10. See Cent. Hudson, 447 U.S. at 566, 100 S. Ct. 2343. Under 21 U.S.C. § 331(a), a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA approved drug, e.g., making false or misleading statements about a drug.

84. Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id*. at § 331(a) (prohibiting distribution of a misbranded drug); *id*. at § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

85. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6), et seq. ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6).

86. Thus, companies like Mallinckrodt may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by government programs, including Medicare and Medicaid.

87. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." 21 C.F.R. 202.1(e)(6)(iv).

88. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. 21 C.F.R. 202.1(e)(5), et seq. A company violates this regulation if it presents "false or misleading"

information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id*.

89. Section 202.1(1)(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

90. Section 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."

91. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

92. Section 99.101, *et seq.* lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound" 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

93. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable

publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. 99.101(a)(4).

94. Additionally, off-label information may be disseminated only in response to an "unsolicited request from a healthcare practitioner." 21 U.S.C. § 360aaa 6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa (b) & (c); 360aaa 1.

95. The FDA does not generally regulate the exchange of scientific information, but when such information is provided by or on behalf of a drug company regarding one of the company's products, the information may be subject to the labeling and advertising provisions of the law and regulations. For example, while information provided at continuing medical education programs (such as medical conferences and professional gatherings intended to enhance physicians' knowledge and enable them to meet certain practice requirements) generally is not subject to FDA regulation, it will be subject to FDA regulation if the program has been funded and substantially influenced by a drug company.

96. In sum, the off label regulatory regime of the federal government protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

The FDA has limited ability to regulate drug company marketing and promotion.

97. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off label uses. See Statement by Janet Woodcock, M D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

98. DDMAC's effectiveness in regulating off label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-approved. FDA review of promotional materials occurs, if at all, only after the materials already have appeared in public. *See* Woodcock Statement, above. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id*. Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

99. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

100. The FDA's ineffectiveness in policing off label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See* Drugs: FDA

Oversight of the Promotion of Drugs for Off-Label Uses (GAO 08-835), http:1www.gao.gov/new.items/d08835.pdf.

101. Among the Report's findings: (i) FDA does not have separate oversight activities to specifically capture off-label promotion; (ii) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (iii) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (iv) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted materials, for instance, discussions between doctors and sales representatives; (v) during calendar years 2003 through 2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

Mallinckrodt's false and misleading marketing of Acthar for a "mode of action" that is unknown, and for uses and doses that are not approved by the FDA.

102. According to the "Pre-Decisional Agency Memo" issued September 27, 2010 by the DDMAC for Acthar, NDA 022432 ("DDMAC Memo"), the formulation of ACTH now known as H. P. Acthar Gel (Repository Injection), which is known generically as corticotropin, was originally approved by the FDA prior to the 1962 Kefauver-Harris Amendment to the Federal Food, Drug And Cosmetics Act of 1962 ("FDCA"), which introduced the requirement of "substantial evidence" of two adequate and well controlled studies.

103. In its 2010 assessment of Acthar, the DDMAC observed:

> At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance

> for treatment of these individual conditions. A few patients had improvements in hematology data and improvement in symptoms (decreased diarrhea, improved appetite, sense of well-being, etc.) reported to support the efficacy of treatment.
>
> ***
>
> **These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials**.

DDMAC Memo at 2-3 (emphasis supplied).

104. Remarkably in 2017, Mallinckrodt falsely stated that when the FDA reviewed Acthar's label in 2010, it "determined there was sufficient scientific evidence and clinical evidence to support the 19 indications now in the current label." Mallinckrodt Statement on H.P. Acthar Gel (Repository Corticotropin Injection) Update, dated June 22, 2017 ("Mallinckrodt 2017 Statement"). The Mallinckrodt 2017 Statement claimed to "[t]o address the false and misleading information about Mallinckrodt Pharmaceuticals and its product H.P. Acthar Gel," when in point-of-fact, it did the opposite: it presented a demonstrably false and misleading picture about Acthar's safety (including the increasing incidence of adverse events), efficacy and approval by the FDA.

105. In fact, directly contradicting Mallinckrodt's false claims about the alleged "sufficiency of scientific evidence," the Director of the Division of Neurology Products, Dr Russell Katz, wrote:

> The **sponsor [Mallinckrodt] had not conducted any trials of its own**, and, in brief, we determined that the sponsor should attempt to obtain primary data for several trials published in the archival literature that, potentially, could provide substantial evidence of effectiveness for Acthar Gel for IS.
>
> * * *
>
> The data that the sponsor has provided differ considerably from that typically submitted in an NDA. As noted earlier, **none of the studies were commissioned or conducted by the sponsor, and detailed**

> **protocols, and, in particular, detailed statistical plans for the analyses of these studies, did not exist.**

April 5, 2010 Memorandum from Russell Katz, M.D. at 1, 9 (available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf) (emphasis supplied).

106. Mallinckrodt continued to press its false and misleading narrative about the FDA's purported "approv[al] for 19 indications … following a full label review by the Agency in 2010" into 2018, when Local 322 began to pay for Acthar. *See* Mallinckrodt Statement, "Facts About H.P. Acthar Gel, H.P. Acthar Gel Value to Patients" dated June 29, 2018 ("Mallinckrodt 2018 Statement").

Acthar's DESI review and narrowing of approved indications due to a lack of proven efficacy and safety.

107. Despite published reports that Acthar was somehow "grandfathered" by the FDA, in truth Acthar was subjected to a Drug Efficacy Study Implementation (DESI) review in the early 1970s. The FDA has always required proof of safety and efficacy for the approval of prescription drugs.

108. At the time of the 1962 amendments to the FDCA, there were thousands of drugs on the market whose effectiveness was suspect or altogether unknown. The amendments thus required the FDA to withdraw prior approval of a drug if it found: "on the basis of new information before [it] with respect to such drug, evaluated together with the evidence available to [it] when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." FDCA, 21 U.S.C. § 355(e).

109. Acthar was thus subjected to a DESI review in 1971, and was found to be effective only for a narrow subset of indicated uses. The 1971 report titled "Corticotropin for Parenteral Use", Federal Register, Vol. 36, No. 152 (Aug. 6, 1971) at 14509-14510, found Acthar "lacking substantial evidence of effectiveness" for its "recommended use" in over 30 of its originally approved indications. With respect to certain of the remaining indications, the FDA found Acthar "probably effective"; for others, the FDA found "these drugs are regarded as possibly effective for their labeled indications." *Id*. at 14510.

110. In 1977, the FDA issued a "Follow Up Notice and Opportunity for Hearing", Federal Register, Vol. 42, No. 40 (March 1, 1977) at 11891-11892, in which it reported:

> [on] August 6, 1971, the [FDA] announced its conclusions that the drug products described below [including Acthar] are effective, probably effective, possibly effective, and lacking substantial evidence of effectiveness for their various labeled indications. The notice provided an opportunity for a hearing for the indications concluded at the time to lack substantial evidence of effectiveness. **No data in support of any of the less-than-effective indications were submitted. All such indications are now reclassified to lacking substantial evidence of effectiveness. …No person requested a hearing concerning them, and they are no longer allowable in the labeling**.
>
> ***
>
> **The drugs now lack substantial evidence of effectiveness for the indications evaluated as probably and possibly effective for the indications evaluated as probably and possibly effective in the August 6, 1971 notice**.

Id. (brackets added)(emphasis supplied).

111. As a result, Acthar was left with about 19 narrow indications. For instance, in the area of "rheumatic disorders", the disease for which Acthar was prescribed for Local 322's beneficiary, Acthar was approved only "as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in … rheumatoid arthritis". *Id.* at 11892 (parenthetical in original).

112. All other indications had been "reclassified to lacking substantial evidence of effectiveness" by the FDA. Nevertheless, Mallinckrodt has continued to tout Acthar's original approval in 1952 for "over 50 indications" in an effort to convince physicians, patients and TPPs that Acthar is widely approved to treat array of diseases, as opposed to just the 19 narrow indications for which it is actually approved. See listing of approved conditions below.

113. By the 1960s, Acthar was essentially a generic drug. Injectable ACTH medications faced a variety of competing products. *See Armour & Co. v. Wilson & Co.*, 274 F.2d at 145 ("Both Armour and Wilson manufacture and sell gelatin-ACTH preparations . . . . Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies . . . produce similar products").

114. For the majority of the Acthar's drug lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms ("IS") which was originally an "off-label" indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at $40 per vial and accounted for less than a million dollars of revenue for Aventis, the then-owner.

115. Because prednisone is equally efficacious as Acthar, it has the same risks and benefits as Acthar, but at a far cheaper price. According to GoodRx.com, prednisone is available at leading retail pharmacies for little more than $4 (with coupons), including Walmart, Target, CVS, Walgreens and Giant.

116. Despite this, Mallinckrodt has continually marketed Acthar as the new and improved prednisone, but without any support through head-to-head studies with prednisone. While prednisone has been proven to be safe and effective for the vast majority of indications on

Acthar's label, there is no data to support Mallinckrodt's claims that Acthar is equally or more efficacious than prednisone, or other corticosteroids, so as to warrant even the same price as prednisone, let alone the exorbitant price of Acthar.

117. The same is true of Solu-Medrol (methylprednisone), a synthetic corticosteroid used to treat some of the same conditions for which Mallinckrodt promotes Acthar. Specifically, Solu-Medrol is given to people with multiple sclerosis ("MS") to shorten relapses. The cost of Solu-Medrol is around the same price as what Acthar used to cost, before Mallinckrodt acquired the product in 2001.

118. To try to deflect attention from the stark price differences between Acthar and generic prednisone, Mallinckrodt has engaged a small army of dedicated, highly-paid spokes-doctors as KOLs to work with Mallinckrodt MSLs and its large sales force to promote sales of Acthar to the KOLs' peers. These KOLs work with Mallinckrodt and UBC to circumvent and bypass protections and controls imposed by TPPs to control and limit their expenditures on high-priced specialty drugs, like Acthar.

119. One major control utilized by payors is a "prior authorization" ("PA") process whereby a prescription for high-priced specialty medication like Acthar must be reviewed and authorized before the script written by the doctor is filled and charged to the TPP. However, Mallinckrodt and UBC have systematically circumvented such controls by their insistence that all patients and providers signing the blanket consents included on the Acthar Start Form at Exhibit "A" hereto, put in place in 2007 as part of the "new strategy". All such forms are faxed to UBC and processed through the "HUB" as described below, ensuring that unapproved uses and doses, like those prescribed to the beneficiaries of Plumbers Local 322 and other TPPs in the Class, are paid for at Acthar's inflated AWP as set by Mallinckrodt and Cigna/Express Scripts.

Acthar's approved label indications.

120. As stated above, the FDA has approved Acthar for multiple, but limited, indications. These narrow indications, as set forth in the FDA-approved label, are:

a. As monotherapy for the treatment of infantile spasms ("**IS**") in infants and children under two years of age;

b. For the treatment of acute exacerbations of Multiple Sclerosis ("**MS**") in adults;

c. As adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in the following Rheumatic Disorders: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis (collectively, "**RA**");

d. During an exacerbation or as maintenance therapy in selected cases of the following Collagen Diseases: systemic lupus, erythematosus, systemic dermatomyositis (polymyositis)(collectively, "**SLE**");

e. For the following Dermatologic Diseases: Severe erythema multiform and Stevens-Johnson syndrome;

f. For serum sickness;

g. For symptomatic sarcoidosis;

h. To induce a diuresis or a remission of proteinuria in the nephrotic syndrome ("**NS**") without uremia of the idiopathic type or that due to lupus erythematosus.

121. Despite these many, narrow indications, substantially all of Mallinckrodt's sales have been generated from just five of these indications: (1) IS, (2) MS, (3) SLE, (4) NS, and (5) RA.

Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE) Nephrology Syndrome (NS) and Rheumatoid Arthritis (RA).

Multiple Sclerosis

122. Multiple sclerosis ("MS") is a central nervous system disease in which the body's

immune system attacks the body's myelin nerve cell coating. MS can cause a variety of symptoms, which can increase in severity periodically.

123. MS "relapses," "acute exacerbations," or "flares" (collectively "MS exacerbations") are temporary periods of increased disease activity in an MS patient, manifested by the worsening of existing MS symptoms or the onset of other MS symptoms. MS exacerbations are not a separate disease from MS.

124. The FDA has approved several medications for the long-term treatment of MS patients, including medications to slow the accumulation of physical disability from the disease or to decrease the frequency of acute exacerbations. These medications are sometimes referred to as MS "disease modifying" drugs or therapies. Acthar is not a "disease modifying" drug or therapy for MS.

125. The FDA also has approved drugs for treatment of MS exacerbations, such as Acthar. A standard treatment for MS exacerbations includes administering methylprednisolone, a steroid, which can be administered intravenously ("IVMP") or orally. One such treatment is Solu-Medrol. Both IVMP and oral methylprednisolone are available in several brand name or generic forms. The drugs are significantly less expensive than Acthar. Depending on the pharmacy from which it is obtained, generic methylprednisolone can be had for as little as $34 per gram, without coupon.

Systemic Lupus Erythematosus

126. Systemic lupus erythematosus ("SLE") is an autoimmune disease in which the body's immune system targets its own healthy cells. Lupus can damage the kidneys, brain, skin, joints, or other areas of the body.

127. SLE patients can experience "flares" or "exacerbations' (collectively "SLE

exacerbations"), which are periods of increased disease activity and are characterized by worsening SLE symptoms.

128. SLE exacerbations are not a separate disease from SLE.

129. A standard treatment for SLE exacerbations includes the administration of steroids, which can be available in brand name or generic forms. The drugs are significantly less expensive than Acthar.

Nephrology Syndrome

130. Nephrology syndrome ("NS") is a kidney disease that causes one's body to excrete too much protein in the urine. NS is usually caused by damage to the clusters of small blood vessels in one's kidneys that filter waste and excess water from the blood.

131. A standard treatment for NS includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

Rheumatoid Arthritis

132. Rheumatoid arthritis ("RA") is an inflammatory autoimmune disease in which the body's immune system targets itself, including the joints. RA patients can experience "flares" or "exacerbations" (collectively, "RA exacerbations"), which are periods of increased disease activity and are characterized by worsening RA symptoms.

133. RA exacerbations are not a separate disease from RA.

134. A standard treatment for RA exacerbations includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

Dangers of Acthar for unapproved uses and doses

135. Acthar is a dangerous drug with wide ranging and potentially life-threatening adverse effects. Thus, its FDA-approved label specifically warns that patients taking Acthar may suffer the following adverse effects:

a. increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections, although signs and symptoms may be masked;

b. adrenal insufficiency;

c. Cushing's Syndrome;

d. elevated blood pressure;

e. masking of symptoms of other underlying diseases and disorders;

f. gastrointestinal perforation and bleeding;

g. behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis;

h. comorbid diseases, such that symptoms of diabetes and myasthenia gravis may be worsened;

i. ophthalmic effects, such as cataracts, infections and glaucoma;

j. loss of endogenous activity;

k. enhanced hypothyroidism or liver cirrhosis for patients already suffering from these conditions'

l. negative effects on pediatric growth and physical development;

m. decrease in bone density; and

n. potential fetal harm in patients who are pregnant, or may become pregnant.

136. Additionally, the FDA-approved label warns that patients taking immune suppressive doses of Acthar should not be administered live or attenuated vaccines.

137. In view of Acthar's unusual safety profile, the FDA took the additional, non-

standard step when it approved Acthar for the treatment of IS in 2010 of also approving a Risk Evaluation and Mitigation Strategy (REMS) that requires Mallinckrodt to distribute an approved Medication Guide with each prescription, and also to submit REMS Assessments to the FDA at periodic intervals following approval of the REMS. The approved Medication Guide elaborates on the serious and significant side effects associated with Acthar.

B. THE ACTHAR "DISTRIBUTION SCHEME"

Questcor acquires Acthar from Aventis.

138. In 2001, Questcor acquired Acthar from Aventis Pharmaceutical Products, Inc. ("Aventis") for only $100,000, but in 2014 Mallinckrodt acquired Questcor for approximately $5.9 billion.

139. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with the FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

140. Acthar's value was limited because it was the "gold standard" for treating only one condition, infantile spasms ("IS"). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. In 2010, the IS indication was approved by the FDA, and orphan drug status was granted.

141. Between 2001 – 2007, Acthar's primary sales were for the treatment of IS, despite its off-label indication.

Sigma Tau's Ownership and Control of Questcor, and the Launch of the "New Strategy".

142. In 2001, Questcor was floundering as a company until it got millions of dollars from Sigma Tau Finanziaria, an Italian drug conglomerate run by brothers Claudio and Paolo Cavazza, giving the Cavazzas and Sigma-Tau approximately 31% of the common stock outstanding as of March 15, 2002 and making them the largest shareholder in Questcor. Indeed, in its 2001 10-K, Questcor admitted that "these shareholders can control the outcome of certain shareholder votes, including votes on election of directors, … and other significant corporate transactions."

143. In addition, the Cavazzas owned warrants to purchase another 2,559,494 shares of common stock, as well as a $2.0 million 8% convertible debenture, giving them even greater control over Questcor and its decision-making.

144. According to Questcor's public filings, the company reported the following:

> In April 2001, we entered into a Stock and Warrant Purchase Agreement with Sigma-Tau Finance Holding S.A. ("Sigma-Tau") pursuant to which Sigma-Tau purchased (i) an aggregate of 2,873,563 shares of common stock at a purchase price of $0.52 per share, for an aggregate purchase price of $1,500,000, and (ii) a warrant to purchase an additional 2,873,563 shares of common stock at a purchase price of $0.52 per share. In May 2001, as required under the rules of AMEX, we sought and received shareholder approval to allow for full exercise of the warrant. In July 2001, Sigma-Tau assigned the warrant to Paolo Cavazza and Claudio Cavazza, the principal shareholders of Sigma-Tau, who exercised the warrant in full, purchasing 2,873,563 shares of common stock at a purchase price of $0.52 per share, resulting in aggregate proceeds to us of $1,500,000 (including the $100,000 originally paid by Sigma-Tau to acquire the warrant).
>
> In July 2001, concurrent with our agreement to acquire Acthar from Aventis, we entered into a Stock Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased 5,279,034 shares of common stock at a purchase price of $0.66 per share, for an aggregate purchase price of $3,500,000.

> In December 2001, we entered into a Promotion Agreement with VSL Pharmaceuticals, Inc., a private company owned in part by the principal shareholders of Sigma-Tau, to promote, sell and distribute the product VSL#3 in the U.S. In connection with this Promotion Agreement, we entered into two Stock and Warrant Purchase Agreements, one with Paolo Cavazza and one with Claudio Cavazza, to purchase (i) an aggregate of 640,000 shares of common stock for a purchase price of $1.50 per share (representing a twenty percent premium to our market price for the five days prior to execution of the Purchase Agreements), for an aggregate purchase price of $960,000, and (ii) warrants, at an aggregate purchase price of $300,000, to purchase an additional 1,800,000 shares of common stock at a purchase price of $1.75 per share before December 1, 2003. We issued the common stock related to this transaction in February 2002. Additionally, in connection with this transaction, we entered into a standstill agreement with Sigma-Tau whereby Sigma-Tau and its affiliates agreed to limit purchases of common stock on the open market to no more that 2,000,000 shares through July 2003. Assuming Sigma-Tau exercises its warrants in full, they would own approximately 34% (including the 640,000 shares of common stock issued in February 2002) of our outstanding common stock as of December 31, 2001.
>
> ***
>
> On March 15, 2002, in two separate transactions, we issued $4.0 million of 8% convertible debentures to an institutional investor and Sigma-Tau. We will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into shares of our common stock at a fixed conversion price of $1.58 per share (subject to adjustment for stock splits and reclassifications). At the end of the term of the debenture, under certain circumstances, we have the option to repay the principal in stock and, under certain circumstances, we can also redeem the debenture for cash prior to maturity. The debentures mature on March 15, 2005. In conjunction with this transaction, we issued warrants to both the institutional investor and Sigma-Tau to acquire an aggregate of 1,518,988 shares of common stock at an exercise price of $1.70 per share. Both warrants expire on March 15, 2006….

145. Importantly, a few years earlier, Claudio Cavazza had earned notoriety, and 1 ½ years of probation, for his role in a 1993 scandal in which he admitted paying kickbacks to health officials to get Sigma Tau products onto Italy's national drug formulary at increasingly higher prices. He also reportedly delivered bribes on behalf of other drug companies.

146. But Claudio's criminal record, a record of bribes to force payers to overpay for prescription drugs, did not stop Questcor from taking the Cavazzas' money and ceding effective control of the company to the Cavazza brothers in conjunction with Questcor's acquisition of Acthar.

147. Instead, Questcor allowed the Cavazzas to build their ownership stake in Questcor to more than 30%, giving them substantial control over Questcor's Board of Directors.

148. The Cavazzas used that control to install one of their own, Gregg LaPointe, to the Questcor Board of Directors.

149. In 2001, LaPointe was the Vice-President of Finance for Sigma Tau Pharmaceuticals, Inc. of Gaithersburg, Maryland ("Sigma-Tau Pharma"). Sigma Tau Pharma was the wholly-owned, U.S. subsidiary of Sigma-Tau. By 2003, LaPointe was the Chief Operating Officer ("COO") of Sigma Tau Pharma. He was elevated to CEO in April 2007, in conjunction with his adoption of the below-described "new strategy" for Questcor's sale of Acthar.

150. With the Cavazzas effectively in control, and now with LaPointe on the Questcor Board, the situation was ripe for fraud and abuse with Acthar, the likes of which have never been seen before, especially with a prescription drug of such limited therapeutic value.

Mallinckrodt Adopts a "New Strategy" to Restrict Acthar Distribution and Aggressively Market Acthar for Unapproved Uses and Doses Through a Scheme of Kickbacks and Inducements

151. Acthar is a specialty pharmaceutical distributed directly to patients, like the beneficiaries of Local 322 in this case.

152. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor

acquired the rights to Acthar, it initially maintained that broad distribution network.

153. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers "A", "B", and "C" in its 2007 10-K, to just Cigna/Express Scripts.

154. The goal of this "new strategy" was to lock patients into receiving Acthar through one distribution channel controlled by Mallinckrodt, and to ensure prescription distribution and payment through one source, UBC. UBC is Mallinckrodt's self-described "HUB" of operations for Acthar. Mallinckrodt has maintained this exclusive arrangement with UBC since 2007.

155. However, the original officers and directors of Mallinckrodt did not agree with the "new strategy". Accordingly, two Directors on the Mallinckrodt Board engineered a coup to take over the company, to replace the CEO and to have the company adopt the new strategy.

156. Mallinckrodt's "new strategy" was the brainchild of Defendant Gregg LaPointe, a critical member of the Questcor Board of Directors installed by the largest shareholders, the Cavazzas. LaPointe also served as a member of the Corporate Council of the National Organization for Rare Diseases ("NORD"), which served as an important player in Mallinckrodt's and UBC's scheme to minimize resistance and pushback by patients and physicians to Acthar's higher prices by serving as a leading distributor of free Acthar supplied by Mallinckrodt to patients who could not afford to pay the newly established new high prices.

157. LaPointe convinced Steve Cartt, Questcor's Chief Operating Officer and Executive Vice-President in charge of sales and marketing of Acthar at the time, that the company should implement the "new strategy" for Acthar.

158. Cartt and LaPointe approached then-Questcor Board member Don Bailey to garner his support for the new strategy. Their "offline discussions did not sit well with

Questcor's President and CEO at the time, James L. Fares.

159. In February 2005, James L. Fares was appointed President and CEO of Questcor by the Board of Directors. According to Albert Hanson, the Chairman of the Board, "the Board sought an accomplished pharmaceutical executive with substantial expertise in selling and marketing pharmaceutical products." Chairman Hanson further explained the selection of Feres as follows:

> [T]he Board assessed each candidate's track record and capability to think creatively about Questcor's business. Such skills are critical in developing and executing a successful long-term strategy for a specialty pharmaceutical business. We looked for a talented executive who understood the specialty pharmaceutical market and had demonstrated the leadership skills necessary to create shareholder value. We believe that in Jim Fares we have found that executive. His successful track record in sales, marketing, business development, and general management, coupled with his energy and enthusiasm for pharmaceuticals, convinced us that we had found the right individual to lead Questcor.

160. Prior to joining Mallinckrodt, Feres held senior management positions at Merck, Athena Neurosciences and Elan Pharma. He founded and served as Sr. Vice President of Commercial Operations at Xcel Pharmaceuticals from 2001 – 2003. In his last position, he served as CEO and President of FGC Pharm/Novella Neurosciences. In sum, Feres was well qualified to lead a company like Mallinckrodt.

161. Feres resigned in May 2007, after taking the below-described 30% price increase for Acthar in February 2007. He was replaced by Don Bailey, whom the Board first appointed as Interim President, but then elevated to full-time President and CEO in conjunction with Mallinckrodt's adoption of the new strategy.

162. In sum, Bailey was not well qualified to lead a prescription drug company like Mallinckrodt. But he was willing to jettison responsible and ethical business practices in favor of the "new strategy", with unconscionable price increases [the Pricing Scheme] and an

aggressive campaign of off label promotion fueled by misrepresentations and deception about Acthar's price, MOA, approved indications and doses, and value. For that, he was rewarded by being appointed the company CEO.

163. Mallinckrodt then signed contracts with CuraScript and UBC in late June 2007 for the exclusive distribution of Acthar and exclusive operation of the HUB for ASAP.

164. Mallinckrodt and UBC then began to promote Acthar aggressively pursuant to the Pricing Scheme and Marketing Scheme detailed below. They did so to overcome resistance by providers, patients, and TPPs (like Plumbers Local 322) to the high cost and limited value of Acthar.

165. Shortly thereafter, in July 2007, three Board members resigned, including the Chairman Albert Hanson.

166. In addition to CEO Feres, Mallinckrodt's Sr. Vice President of Strategic Planning and Communications, Eric Liebler, also quit. Liebler quit less than a year after being hired. He quit just three weeks after the "new strategy" was announced.

167. LaPointe also resigned within a week of the new strategy being launched, but not because he disagreed with the new strategy. Quite the contrary: his work on behalf of the Cavazzas was done. The Cavazzas had accomplished was they set out to do, engineering a coup at Questcor to take the company on an aggressive path centered around the new strategy and the three schemes detailed herein, the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Without LaPointe's installment on the Questcor Board, this would not have been possible.

168. These facts were confirmed by Questcor COO Steve Cartt on September 6, 2007, when he wrote to all senior staff at Questcor the following about LaPointe's departure:

> Subject: Lapointe departure
>
> Wanted to give you all a heads-up that Gregg LaPointe has left the Board of Directors (see attached link). This has been expected for some time actually, and is no cause for concern. Gregg joined the Board so that Sigma Tau could have some visibility on how Questcor was being run and the strategy going forward for the company. He actually as you can imagine ended up spending far more time on Questcor business over the last year than he ever imagined. Sigma Tau, our largest shareholder, is now comfortable with the company's path forward now, and is interested in having Gregg fully focused on Sigma Tau's own US business going forward, so the decision was made.
>
> Also, in case you were wondering, Gregg has been a big supporter of the pricing strategy from the very beginning, so his departure was not the result of any disagreement with strategy. Quite the contrary actually.
>
> Let me know if you have questions. Thanks, Steve.

169. It is believed and therefore averred that this mass exodus of leading executives and Board members was caused by Mallinckrodt's decision to adopt the "new strategy", with the Distribution Scheme, the Pricing Scheme and the Marketing Scheme as the hallmarks of an overarching scheme to raise Acthar prices, and overcome TPP resistance to high drug prices.

170. The decision to change the distribution, pricing and marketing strategies for Acthar was highly lucrative for all who supported it.

171. For instance, between 2006-2007, Don Bailey was permitted to purchase tens of thousands of shares of Questcor stock for $1.67 per share. He also received warrants to buy tens of thousands of additional shares of stock at just $0.44 per share. After the new strategy was pushed through, and the company started gouging patients and payers for Acthar, Bailey sold his shares, making tens of millions in profits.

172. Bailey's last warrant exercise and sale of Questcor stock took place in the summer of 2014, just prior to Mallinckrodt's purchase of Questcor. He exercised warrants to purchase

40,000 shares of common stock at $5.12 (at a total cost of $204,800). He then sold the same stock one month later at $91.96 per share (at a total price of $3,678,240). This was a profit of more than $3.2 million in one month!

173. All told, Don Bailey earned tens of millions of dollars in just over 7 years through his insider stock sales alone, not counting his lucrative executive and Board member package of salary and benefits.

174. The self-described "orphan drug strategy" worked as follows: despite the fact that Acthar was an older drug, Mallinckrodt would "re-launch" Acthar with a new, limited distribution system and a substantially higher price, to make it appear as if Acthar were a new product being launched as the only product indicated for IS, an off-label indication at the time.

175. The IS market was a captive market involving a life-threatening disease afflicting infant children. Like other debilitating or life-threatening, orphan conditions, for which there was only one, sole-source drug treatment, IS presented Mallinckrodt with an opportunity to leverage its position against a particularly fragile, powerless patient population in an extremely narrow market.

176. As a result, Mallinckrodt predicted that the IS market would likely be able to absorb a much higher price with little resistance. In contrast, Mallinckrodt feared that the market for drug treatments of other disease states, such as the MS market, would not tolerate such a high price. Nevertheless, Mallinckrodt only viewed the anticipated resistance to higher prices by patients and payors as a challenge to be overcome.

177. Mallinckrodt and Cigna/Express Scripts' UBC overcame such challenge in several ways, as part of a new marketing and sales scheme, including the following:

(i) knowingly disregarding federal laws and FDA regulations prohibiting off-label marketing and promotion;

(ii) knowingly misrepresenting the purported efficacy, safety and value of Acthar for the treatment of unapproved conditions and unapproved doses in promotional and marketing material not submitted to, reviewed by, or approved by the FDA;

(iii) failing to disclose and submit to the FDA all of their promotion, advertisements and marketing materials, as required by law;

(iv) promoting the sale of Acthar for uses that were not proven to be safe or effective, as required by law;

(v) promoting the sale of Acthar for doses that were not proven to be safe or effective, as required by law;

(vi) willfully underreporting adverse events, as required by law;

(vii) utilizing improper, false and misleading comparative marketing tactics, such as comparing Acthar to prednisone, and including unsubstantiated superiority and value claims; and

(viii) improperly compensating healthcare professionals with free vials of Acthar, speaking and consultant fees and benefits, and other kickbacks as an inducement to induce them to promote and prescribed Acthar to their patients.

(ix) operating patient assistance programs as a means to secretly channel funds to third parties to pay for patient copay obligations, to remove patient complaints about the high costs of Acthar, and to force TPPs like Plumbers Local 322 to pick up the balance of the Acthar bill.

178. The new pricing established by Mallinckrodt under the Pricing Scheme was only limited by what Mallinckrodt predicted that payors, like Plumbers Local 322, would be willing to bear. This was because the Marketing Scheme adopted at the same time ensured that the promotional message delivered by UBC, as well as Mallinckrodt sales representatives and MSL's, was false, misleading and deceptive, and backed by unlawful kickbacks and inducements.

179. Mallinckrodt Executive Vice-President, Steve Cartt, admitted "'[w]e did some market research,' . . . [t]alking to physicians and others about pricing 'gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would

pay' . . . . 'The reality was better than we expected.'"[6]

The Acthar Support & Access Program and the UBC "HUB".

180. One of the primary means by which Defendants carried out their unlawful scheme and conspiracy was through a program known as the "Acthar Support & Access Program" or "ASAP." This program was structured to ensure that Mallinckrodt could ship its Acthar directly to patients, and then receive guaranteed payments directly from the TPPs who provide prescription drug coverage for their beneficiaries.

181. The ASAP was adopted by Mallinckrodt and Cigna/Express Scripts in 2007, as part of the "new strategy". UBC's predecessor (Healthbridge) became the exclusive operator of the ASAP program for Mallinckrodt.

182. Under the ASAP, all Acthar prescriptions are routed through UBC to patients, and all Acthar payments are coordinated by UBC to Mallinckrodt.

183. This process is generally laid out in the Acthar Start Form provided by Mallinckrodt (at Exhibit "A" hereto).

184. Once the patient (or their physician) seeks a prescription of Acthar, they are directed to UBC by Mallinckrodt's sales representatives, MSLs or KOLs. They are then required to fill out and fax back to UBC the Acthar Start Form in order to obtain Acthar. There is no other way to get Acthar.

185. Upon receipt of the Acthar Start Form, UBC confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient's insurance coverage or other source of payment. UBC then arranges for the Acthar to be delivered directly

[6] Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled The Middleman's Markup in New York Print Ed.)(hereinafter, "*Fruedenheim*").

to the patient by CuraScript.

186. Copies of the Acthar Start Form are attached to the Strunck & Pratta Complaint at Exhibit "H" and "I". These Qui Tam Relators have confirmed that this is the process for Acthar.

187. The Acthar Start Form requires the patient and the physician to authorize the prescription as "medically necessary", and to payment as appropriate before Mallinckrodt will ship the Acthar to the patient. Mallinckrodt have used a version of the Acthar Start Form for all year from 2007 through the present. For this entire time period, such forms are required to be faxed to UBC, via the used of the wires.

188. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the "HCP" (or health care professional); (2) a patient authorization requiring signature by the "patient or legal representative"; and (3) information concerning Acthar indications and usage. The required signature of the patient authorizes "Mallinckrodt and its agents" to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, "including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, 'Designated Parties')" to provide Acthar and receive payment, among other things.

189. Specifically, the patient authorizes Mallinckrodt and UBC, its "Designated operator", "to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training." In other words, the patient directly authorizes UBC, as Mallinckrodt's agent, to ship Acthar directly to them, and to receive payment from both the patient (for the co-pay) and the TPP prior to obtaining the medication.

Direct Injury of Plaintiff and the Class.

190. By the above-stated arrangements, Acthar product flows from Mallinckrodt and Cigna/Express Scripts to the patient, while the money flows from the patient and payor back to Mallinckrodt. It starts with sales representatives, like Pratta, detailing medical providers in New Jersey about the "mode of action", uses, benefits, and "value" of Acthar, in relation to other medications and treatments.

191. Mallinckrodt only "consigns" the Acthar to Cigna/Express Scripts' CuraScript, meaning that Mallinckrodt remains at risk for the sale of the product until it is shipped. Mallinckrodt maintains all right, title and interest to the Acthar until it is approved for delivery by Cigan/Express Scripts' UBC to the patient and payment is assured by the TPP. Both possession and title pass to Acthar pass from Mallinckrodt to the patient and TPP, only after they both agree to pay for it via the Acthar Start Form and UBC's sign-off. UBC's role is to ensure that Mallinckrodt's "risk" is minimal because it will not authorize shipment until payment by the TPP is confirmed. At no time is either CuraScript or UBC at risk for the Acthar sold by Mallinckrodt.

192. In this way, TPPs like Local 322, along with other similarly situated members of the Class, are directly harmed by the conduct of Mallinckrodt, because their beneficiaries receive the Acthar directly from Mallinckrodt, via its designated consignees, at their New Jersey homes to be self-injected, and they make their co-payments, along with the TPPs, directly back to Mallinckrodt through this same arrangement.

193. The Acthar distribution arrangement between Mallinckrodt and Cigna/Express Scripts is illustrated in the following two figures. In Figure 1, the distribution arrangement is described in aggregate.

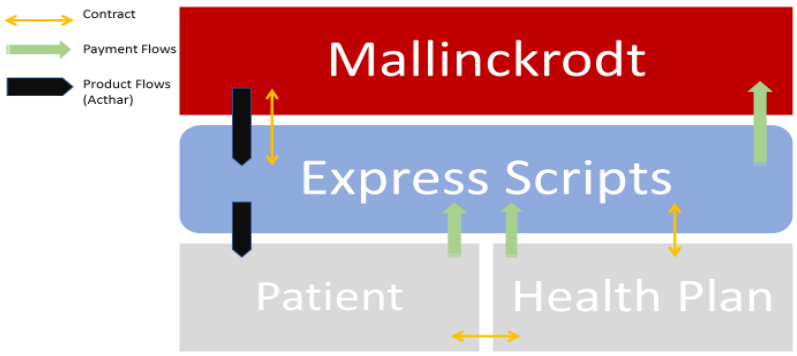

Figure 1

194. Figure 2 below illustrates how Acthar is prescribed, authorized, distributed and paid for through Cigna/Express Scripts. Although these payments pass through Cigna/Express Scripts, payment flows and products flows are ultimately aligned between Mallinckrodt and UBC, Cigna/Express Scripts' reimbursement hub, through a contract with Mallinckrodt to operate the ASAP program, which confirms the medical necessity of the prescription and collects the payment (by Accredo or other specialty pharmacy), and then arranges for shipment and billing (by CuraScript).

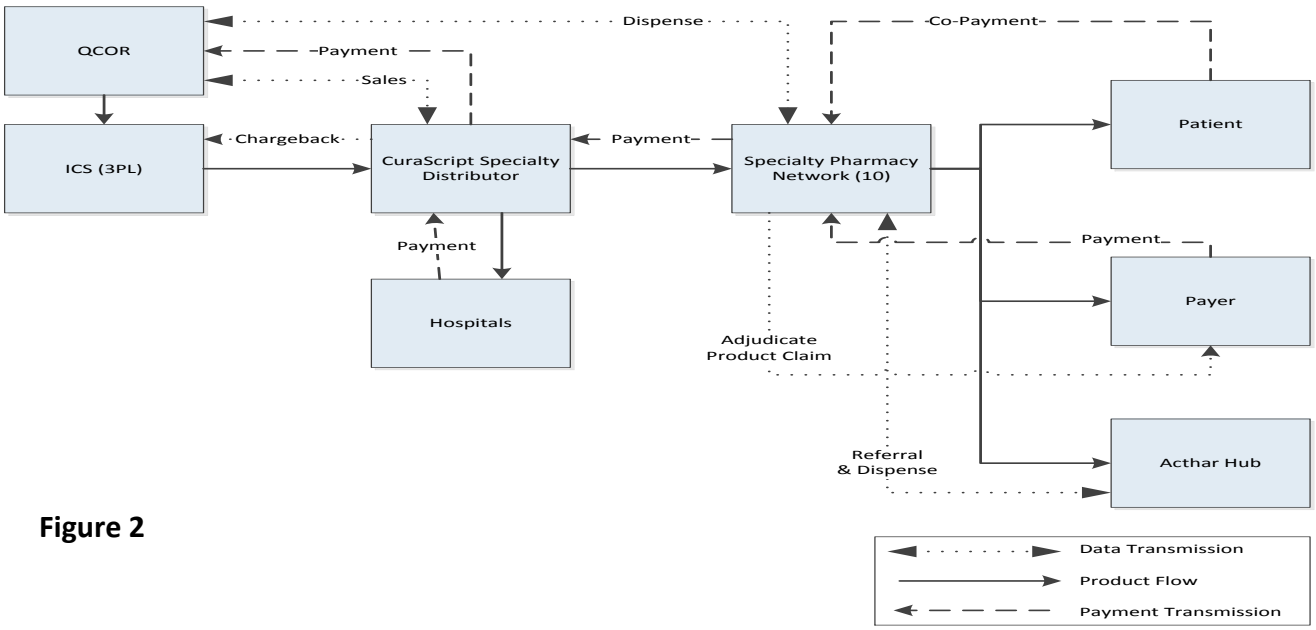

Figure 2

195. Since the launch of the new strategy, CuraScript has contracted directly with Mallinckrodt to ship Acthar. Through such contractual arrangement, Acthar travels from Mallinckrodt directly to the patient, and payments are channeled directly back to Mallinckrodt.

196. The patient, on the other hand, has prescription insurance coverage through his or her health plan, such as that provided by Local 322 to its patient members. In this case, Local 322 administered the health plan that covered its patient members. The health plan has a contract with ESI, which requires ESI to collect payments for the price of Acthar.

197. By these arrangements, the Acthar product flows directly from Mallinckrodt through Express Scripts to the patient, while the money flows directly from the patient and payor through Express Scripts back to Mallinckrodt.

198. Wielding both the largest collection of patients in the United States and a direct shipment channel for specialty drugs, Express Scripts is in a unique position to negotiate the most competitive, discount prices for specialty drugs in the United States. This bargaining power has allowed Express Scripts to push back against attempts by pharmaceutical drug manufacturers to charge inflated prices for drugs above the actual market value of the drugs.

199. This is a distinguishing feature of specialty drugs in general, from other brand name and generic drugs available at retail pharmacies, who received the drugs from wholesalers, who directly contract with drug manufacturers. Here, Mallinckrodt and Express Scripts removed all the middlemen. There are no wholesalers or retailers between the patients and TPPs and the Mallinckrodt and its agents.

200. Further, Plaintiff and TPP members of the Class have paid the inflated AWPs directly set and charged by Mallinckrodt. As a result, their injury is both cognizable – economic injury from a price overcharge – and direct – paying the price set and charged by the Defendant

sued. The Class does not include any other potential payors who may have paid some other price than the inflated AWPs for Acthar.

201. Mallinckrodt and Cigna/Express Scripts' UBC also uniquely interact directly with TPPs and their New Jersey based beneficiaries in this case to ensure their scheme is successful. Beyond direct consultation, they provide "Home Injection Training Services" or "HITS", by which Mallinckrodt pays to have a nurse visit the patient to teach them how to self-inject the Acthar. UBC arranges for HITS, and tracks all such interactions through a database maintained for Mallinckrodt. All bills for such HITS are paid by Mallinckrodt, who is happy to provide free injection training to remove any potential obstacle to a patient taking Acthar.

202. All these functions are coordinated in the first instance by the Mallinckrodt sales representatives, like Lisa Pratta, working with doctors and all aspects of Cigna/Express Scripts to ensure the prescription of Acthar is made, filled, and paid for by TPPs, like Plumbers Local 322. They do so by engaging in the unlawful conduct alleged herein, promoting Acthar for a mode of action that is unknown, for uses and at doses that are not FDA-approved, with co-pay and other patient assistance to ensure that TPPs are billed, regardless of whether the patient can afford the medication.

203. The Acthar Start Form (Exhibit "A" hereto), by which all Acthar is prescribed, has section for the provider to request HITS for the patient.

204. These direct interactions between the Defendants and the Class give Plaintiff and the Class standing to sue on all counts. At a minimum, they raise serious fact questions about the uniqueness of Defendants' scheme to allow this case to proceed to discovery.

205. Mallinckrodt leveraged and enhanced its monopoly power by limiting the distribution of its sole specialty drug to just one specialty pharmacy distributor, CuraScript, and

employing as its agents ESI's Accredo and UBC, along with CuraScript, to coordinate all aspects of the distribution and sales of Acthar: from prescription by the physician, to direct home delivery to the patient, to direct reimbursement by the payor. This allowed Mallinckrodt to raise its prices tenfold initially, and nearly double in the ensuing years.

206. Mallinckrodt Executive Vice-President Steve Cartt admitted, "'[w]e did some market research,' . . . [t]alking to physicians and others about pricing 'gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would pay' . . . 'The reality was better than we expected.' " *See,* Milt Freudenheim, Benefit Managers Profit by Specialty Drug Rights, New York Times, C1, April 19, 2008 (titled, "The Middleman's Markup" in New York Print Ed.)(hereinafter, "Freudenheim").

C. THE ACTHAR "PRICING SCHEME"

Defendants raise the AWPs for Acthar, and charge such prices to TPPs, without regard for the lack of proven safety, efficacy or value of the drug to treat the diseases for which they market and sell Acthar.

207. Mallinckrodt acquired the rights to Acthar from Aventis in July 2001.

208. At the time of its acquisition, the end payor price of a vial of Acthar charged to TPPs, like the Plaintiff, was approximately $40.00.

209. After acquisition, Mallinckrodt raised the per-vial price substantially. By September 2001, Mallinckrodt raised the list price for Acthar, or the wholesale acquisition cost ("WAC"), to $748.16. It raised the end payor price, or the average wholesale price ("AWP"), to $935.20.

210. Like other brand name, injectable drug manufacturers, Mallinckrodt adopted a 25% markup factor for its AWP for Acthar. In other words, once Mallinckrodt sets a new WAC, the AWP is calculated at 25% above the new WAC.

211. From 2001 until Mallinckrodt executed its new strategy in 2007, the Acthar WAC grew from $748.16 to $1,650.23, while the AWP grew from $935.20 to $2,062.79 (25% higher than the WAC).

212. The below table reflects the WAC and AWP price changes (and the percentage increase) as implemented by Mallinckrodt from 2001 through February 2007, and as charged by UBC:

DATE	WAC	AWP	% INCREASE
Sept. 21, 2001	$748.16	$935.20	-
June 24, 2002	$782.60	$978.25	4.6
April 1, 2003	$859.20	$1,074.00	9.787
March 1, 2004	$902.00	$1,127.50	4.98
January 1, 2005	$988.00	$1,235.00	9.53
April 1, 2005	$1,037.20	$1,296.50	4.98
January 1, 2006	$1,120.40	$1,400.50	8.0
October, 1, 2006	$1,232.44	$1,540.55	10.0
December 21, 2006	$1,269.41	$1,586.76	3.0
February 2, 2007	$1,650.23	$2,062.79	30.0

213. The double-digit price increase in 2005 and 2006 were not enough, nor as the 30% price increase in February 2007. Mallinckrodt's greed required more.

214. Mallinckrodt implemented its new strategy with UBC on August 27, 2007, they raised the WAC for Acthar from $1,650.23 to $23,269.00. They also raised the AWP for Acthar from $2,062.79 to a staggering $29,086.25 – representing a 1,310% increase in the span of a

month, and a 72,615% increase from the time Mallinckrodt first acquired the drug.

215. Until Mallinckrodt obtained FDA approval for the IS indication in 2010, the price of Acthar remained relatively stable. However, in 2011, Mallinckrodt increased the price of Acthar three times: by 5% on January 3, 2011, by another 5% on June 1, 2011, and then by 6.5% on December 27, 2011. These three price increases totaled a staggering 16.5% in one year. As of 2012, Acthar's end payor price/AWP stood at $34,150.00.

216. But Mallinckrodt and UBC were wary of TPP's increasing concerns about Acthar's price and lack of proven value for the various indications being promoted. A poignant example is the attempted price increase in September of 2012.

217. In September 2012, Mallinckrodt desired to take another 5% price increase. The decision to raise the Acthar price was made by Questcor's COO Steve Cartt in early September.

218. However, on September 19, 2012, health insurer Aetna, announced that it would cut back reimbursements for Acthar, due in part to the lack of evidence of Acthar efficacy for various disease states.

219. Questcor's stock plummeted 56% the same day as the Aetna announcement. Within a week, Questcor's stock had fallen another 37%.

220. Mallinckrodt scrambled to place the intended price increase "on hold for now", due to the Aetna situation. It so advised CuraScript and UBC, which both agreed.

221. This price increase was later taken by the Defendants on June 7, 2013, when the Acthar WAC was increased 5% to $30,120.00 and the Acthar AWP was increased 5% to $37,650.

222. In 2014, Defendants resumed their aggressive price increase strategy, just prior to Mallinckrodt plc's $5.9 billion acquisition of Questcor. But they continued to conceal the truth,

lying to the public about the real reasons for the exorbitant price increases.

223. On January 16, 2014, the Acthar WAC and AWP were raised 5%, to $31,626 and $39,532.50, respectively.

224. Prior to Questcor's acquisition by Mallinckrodt plc in 2014, Questcor had planned an additional 5% increase for Acthar in December 2014. This would have meant a total percentage increase of 10% for the year.

225. However, after the acquisition, Mallinckrodt raised the planned increase to 8.9%, or 13.5% for the year.

226. In the interim, the Executive Committee ("EC") of Mallinckrodt met. The EC consists of the senior management of Mallinckrodt, including President and CEO Mark Trudeau and Executive Vice President and Chief Commercial Officer Hugh O'Neill.

227. COO O'Neill raised the matter of the 8.9% price increase with the EC on Friday December 12, 2014, and it was decided by the Mallinckrodt leadership team to "change[] the magnitude" of the pricing action, reducing the proposed increase from 8.9% to 2%. The EC did this in order to take advantage of an "opportunity for breakthrough pricing strategies" in the future.

228. It is believed and therefore averred that such pricing opportunity was presented by Questcor's prior acquisition of Synacthen, a synthetic version of ACTH.

229. Mallinckrodt had completed its acquisition of Synacthen in 2013.

230. As a result of such Synacthen acquisition, Mallinckrodt was confident that reducing the planned 8.9% Acthar price increase in late 2014 to little more than the consumer price index [which stood at about 1.7% in 2014] -- causing a $26 million shortfall in the forecasted revenues [based on the 5% increase that was "baked in" for December] -- would not

negatively affect the company moving forward. This decision, while ostensibly made against Mallinckrodt's economic self-interest in the short term, was made to further enhance their profits in the long run.

231. Accordingly, with the direct input and hands-on decision-making by President and CEO Trudeau, Mallinckrodt reduced its December 2014 Acthar price increase to 2%. This led to a WAC increase to $32,260.00 and an AWP increase to $40,325.00, respectively, on December 16, 2014.

232. Under Mallinckrodt plc's stewardship, the AWP of Acthar has continued to rise in to well above $40,000 in 2018, when Plumbers Local 322 began paying for it, despite Mallinckrodt's misrepresentations about Acthar's price.

233. In 2018, Mallinckrodt's CEO, Mark Trudeau, deliberately lied to the public in a press release. He willfully misrepresented that "[t]he current 'list price' per vial for the drug is $36,382, not the higher numbers which have appeared in various reports, and Mallinckrodt discounts this list price to both public and private payers." This statement was false, misleading and deceptive.

234. The price paid by "private payers", like Plumbers Local 322 and the Class of TPPs in this case, is the AWP. As set forth above, that price has been in excess of $40,000 since 2014. Mallinckrodt does not "discount" that price to Plumbers Local 322, or any other TPP, as claimed.

235. If Mr. Trudeau was actually representing that the WAC for Acthar was $36,382 as of June 2018, which is not the price paid by "private payers" like Plumbers Local 322, then the AWP paid by private payers would have been actually a staggering $45,477.50, based on the historical 25% markup Mallinckrodt has employed for its Acthar AWPs since the inception of its

ownership in 2001.

236. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown over 100,000% reflecting the precipitous rise in the value of the Acthar assets from $100,000 in 2001 to $5.9 billion in 2014 – a 5,899,900% increase in value. Mallinckrodt has continued to deceive payors like Plumbers Local 322 and the TPP Class about the actual prices of Acthar, and the reasons for its many staggering price increases.

237. In fact, in direct response to a lawsuit filed against Mallinckrodt in April 2017 by the City of Rockford, Illinois, Mallinckrodt issued a public statement, claiming to "set the record straight" about Acthar pricing and other issues. This press release is replete with misrepresentations and deliberate falsehoods that only continues to deceive Plumbers Local 322 and the Class about Acthar pricing and the actual reasons for the high Acthar prices.

238. The 2018 press release was issued by the company CEO Mark Trudeau who falsely, misleadingly and deceptively claimed that the "price of H.P. Acthar Gel today is $38,892, before discounts provided to payers." *Id.*

239. However, when Plumbers Local 322 paid for Acthar in 2018, the Acthar AWP was well over $40,000.00. In fact, the AWP for Acthar had been raised by Mallinckrodt to $40,325.00 on December 16, 2014, 4 years before Trudeau willfully made his materially false statement about Acthar pricing.

240. Today, the price of Acthar stands at over $45,000.

241. Mallinckrodt has conspired and agreed with UBC, and others, to conduct a fraudulent scheme and conspiracy to deliberately inflate the AWPs for Acthar, to maintain such high AWPs for Acthar in the face of complaints by patients and TPPs, like Local 322, to communicate such inflated prices, and to circumvent patient and payor concerns about Acthar's

high prices through the Distribution and Marketing Schemes alleged herein. As Defendants well know, the AWP is used by both government and private assistance programs for prescription drug reimbursement.

242. Government and private assistance programs, like those of Local 322 and the Class, have used the AWPs published in pharmaceutical industry publications, such as the Red Book and Medispan, for years as a basis for reimbursement, in whole or in part.

243. These publications set forth the false AWPs for Acthar, as reported with each price change by Mallinckrodt. In periodically announcing the AWPs for Acthar, the publications simply published the prices supplied to them by Mallinckrodt. Mallinckrodt knew that it could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.

244. This Pricing Scheme allowed Mallinckrodt to control, in conjunction with its Distribution and Marketing Schemes, its profit levels, and the profits of its HUB, UBC, by the direct manipulation and reporting of the Acthar AWP.

245. Years before Mallinckrodt and UBC engaged in their Pricing Scheme to manipulate the Acthar AWPs to increase their profits, in 2003, the Office of Inspector General ("OIG") admonished, "[i]f a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated." In re Pharm. Ind. Average Wholesale Price Litig., 491 F.Supp. 2d 20, 39-44 (D. Mass. 2007). Ironically, this published decision appeared the same month in 2007 that Mallinckrodt and UBC signed their first of many conspiratorial agreements to manipulate and communicate the AWP for Acthar.

246. Plaintiff is not alone in its charge of deceptive conduct against Mallinckrodt. In

April 2015, Mallinckrodt settled a securities fraud class action brought by its investors against the company in January 2013 in the United States District Court for the Central District of California for the sum of $38 million. The securities lawsuit charged the company with, inter alia, "issu(ing) false and misleading statements about the effectiveness of, and prospects for, Questcor's sole product, Acthar." The court denied in part the Defendants' motions to dismiss, allowing certain claims to proceed. The court then granted class certification in November 2014.

247. Following the settlement, Mallinckrodt's CEO Mark Trudeau suggested to investors on October 6, 2015 that drug prices "should be reflective of the value that you deliver to the marketplace."

248. However, following this settlement, and the filing of the Rockford lawsuit, leading executives at PBM Express Scripts (which owned UBC) conceded that Acthar is not worth what Mallinckrodt is charging for it, and what TPPs like Plumbers Local 322 have been paying for it, especially for the treatment of MS, NS and RA. Despite this, neither Mallinckrodt nor UBC have changed their ways.

The Views of Express Scripts' Senior Management On the Lack of Acthar "Value" for the Prices Charged.

249. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, the leading PBM, Express Scripts, did not push back. This likely due to its ownership of CuraScript and UBC, which were both subsidiaries of Express Scripts at the time.

250. However, when confronted about the 2007 price increase in later years, Express Scripts' Chief Medical Officer Steve Miller stated that "[t]he increase was a manufacturing decision. I can't comment on it."[7]

[7] *Freudenheim, supra*.

251. On May 19, 2017, just weeks after Mallinckrodt was sued by the City of Rockford in early April 2017 for, inter alia, price fixing, Express Scripts senior officers made comments about the "somewhat controversial" drug Acthar on a private investor conference call hosted by Citi.8 The Citi interviewer stated, "it's been in the news as – given the pricing around the drug over the past – I don't know – 12 months at least," and then asked for "any thoughts around … how that can be managed and how you see cost of the playing out?" Citi Transcript at 12.

252. In response, Express Scripts' Senior Vice President, Supply Chain and Specialty Pharma, Everett Neville stated:

> I don't think [Acthar is] a very great [drug] – ***it's a pretty poor drug with a very limited need*** and certainly [Express Scripts Chief Medical Officer, Dr,] Steve [Miller] could comment. He's a doctor and I'm just a really bad pharmacist.
>
> …[Y]ou know, and Steve, you could chime in here too, but I think Steve and I both would agree, and ***I think everybody in our company would agree, that the product is vastly overpriced for the value***. ***We don't set the price.*** We've told [Mallinckrodt] that. I personally told [Mallinckrodt's] management team that their drug is hugely overpriced. I know Steve has as well.

Citi Transcript at 12 (emphasis added) (brackets added).

253. Dr. Miller stated that he was in "100% agreement with [Mr.](Everett)." Citi Transcript at 12 (brackets added). He added, "[i]f you look at the data, the indications for the drug are really – while it had, in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace…". Citi Transcript at 12-13.

Mallinckrodt Acquires Acthar from Aventis at a Low Price Reflective of its Lack of Market Value.

[8] *See* Conference Call Transcript of call hosted by the Citigroup Healthcare Team on May 19, 2017 at 11:00a.m. est, with Dr. Steve Miller, Chief Medical Officer from Express Scripts, and Mr. Everett Neville, Senior Vice President of Supply Chain and Specialty (***"Citi Transcript"***).

254. In 2001, Mallinckrodt, then Questcor, acquired Acthar from Aventis Pharmaceutical Products, Inc. ("Aventis") for only $100,000. This low price was reflective of the lack of market value for Acthar for the treatment of disease.

255. But in 2014, seven years after Questcor embarked on its "new strategy" for Acthar, Mallinckrodt acquired Questcor for approximately $5.9 billion.

256. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

257. Acthar's value was limited because it was the "gold standard" for treating only one condition, IS. IS a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. As described above, the IS indication was not approved by the FDA until 2010. Between 2001 and 2010, IS was an off-label indication which Mallinckrodt actively marketed.

258. Between 2001 and 2007, Acthar's primary sales were for the treatment of IS, despite its off-label indication.

259. Consequently, because Mallinckrodt's primary business concerned the off-label marketing and sales of Acthar for IS, it is not surprising that it sought to expand upon such business model in other off label areas, once the IS indication was approved.

260. After the "new strategy" was adopted, Mallinckrodt expanded its marketing for other unapproved uses and doses in MS, NS, SLE and RA. As a result, sales expanded

exponentially in these areas, expanding the profits of the company, all due to Mallinckrodt's company-wide campaign of off label promotion.

261. It was only because of the profits achieved in the areas other than IS that Questcor was deemed worth nearly $6 billion to Mallinckrodt. Consequently, Mallinckrodt has continued to advance the distribution, pricing, marketing and sales schemes initiated by Questcor. These are not "legacy" matters, as Mallinckrodt has falsely claimed. Instead, they have been engrained in Mallinckrodt's business and corporate culture since the early 2000s.

262. For that reason, Plumbers Local 322 and the Class seek declaratory and injunctive relief against Mallinckrodt to put an end to the ongoing schemes for the benefit and future protection of patients and private TPPs, regardless of whether the federal government chooses to settle with Mallinckrodt.

D. THE ACTHAR "MARKETING SCHEME".

263. The Marketing Scheme in this case is identical to the scheme alleged in the Strunck & Pratta and Clark Complaints, and as amended in the U.S. Complaint in Intervention all filed and pending in this Court. The only difference is the affected class of plaintiffs – all private payors as opposed to the government payors in the government's case.

264. To duplicate those factual averments would exponentially and unnecessarily grow the length of this already lengthy Complaint.

265. Nevertheless, Plumbers Local 322 summarizes those averments herein to make clear that it and the Class of TPPs it seeks to represent suffered harm as a result such Marketing Scheme.

As Part of its "New Strategy", Mallinckrodt Creates a Team of Highly-Trained "Medical Sciences Liaisons" to Promote the Sale of Acthar at High Prices Through a Campaign of Misrepresentations and Deception in Conjunction with KOLs.

266. As part of the new strategy in 2007, Mallinckrodt created a new position within the company: "Medical Science Liaison" or "MSL" were highly trained sales employees who were deployed to speak directly to doctors about the safety and efficacy of Acthar for unapproved uses and doses.

267. Mallinckrodt also employed MSLs to provide periodic training to employees of UBC.

268. Such training included information about Acthar's approval uses and doses, as well as its purported safety and efficacy for unapproved uses and doses based upon Mallinckrodt-sponsored "open label" clinical studies, usually conducted by Mallinckrodt-paid KOLs.

269. In the Strunck & Pratta Complaint, they detail the important role the new MSLs played in the Mallinckrodt and UBC schemes alleged. Specifically, the allege:

> Another tactic employed by Questcor to promote H.P. Acthar Gel off-label is to use its Medical Science Liaisons ("MSLs") as an end-run around sales representatives' duty to lawfully promote the drug. Questcor's use of MSLs in this manner is a way for the company to make the unlawful promotional activities for H.P. Acthar Gel appear lawful. *See e.g.* 21 C.F.R. 99.101. et seq.
>
> Medical Science Liaisons are supposed to talk with physicians only about science-to-science issues, and only when those discussions are initiated by the physician. Their primary role is to engage in non-promotional medical activities, and they are not supposed to engage in product promotion. Thus, a sales representative is not permitted to use an MSL as a conduit through which to initiate and pursue off-label promotion activities with physicians.
>
> The law notwithstanding, Questcor erects no wall between its medical and sales staffs, and actively encourages its MSLs to probatively participate in

> promotional activities. Medical Science Liaisons routinely accompany Questcor sales representatives on their sales calls.
>
> Questcor encourages its sales representatives to probatively partner with MSLs to increase H.P. Acthar Sales growth. Commonly, the sales representative will initiate an off-label discussion, and then the MSL will complete the discussion. On other occasions, sales representatives ask their MSL colleagues to contact physicians who are reluctant to prescribe H.P. Acthar Gel for off-label uses in order to attempt to overcome that reluctance whether or not the physician initiated the off-label discussion or requested further information. Again, Questcor ignores that MSLs are not permitted to engage in promotional activities.

Strunck & Pratta Complaint at ¶¶ 142-145.

270. The Relators then proceed to explain the critical role of these MSLs in promoting the off-label use of Acthar, especially for the unapproved, in effective and harmful 5-day dose prescribed to MS patients, like the patients of Local 322 described below. The specifically allege as follows:

> **Five Day Course of Treatment Was Ineffective and Harmful to Patients**
>
> Many physicians have rightfully rejected Questcor's efforts because the 5-day protocol is not supported by any credible evidence, and because experimenting with it cannot be justified in light of its cost and potential for patient harm. However, many physicians have been persuaded to switch from Solu-Medrol to a 5-day course of treatment with H.P. Acthar Gel – in large measure due to the valuable inducements provide to them by Questcor, as described herein.
>
> In Relator Strunck's experience, approximately half the doctors he persuaded to prescribe H.P. Acthar Gel for a five-day course of treatment had to order repeat prescriptions in as few as two to three months due to patient relapse, even though patients treated with Solu-Medrol typically relapse only after twelve to eighteen months. Relator Strunck knows this issue was widespread, because it was regularly was [sic] discussed during regional sales team conference calls. In Relator Pratta's experience, she experienced the same reactions from patients who doctors use the five day [sic] course of treatment.
>
> Questcor's decision to promote H.P. Acthar Gel only for a five-day course of treatment came at the detriment of patients and patient safety. The issue was routinely discussed during regional sales calls and national sales

> meeting, Questcor knew that although a typical patient treated with Solu-Medrol for five days would relapse in twelve to eighteen months, and that a typical patient treated with H.P. Acthar Gel would relapse in as few as two to three months.
>
> Thus, the cost to treat a typical patient with Solu·Medrol would be less than $5,000 over a five-year period (approximately four treatment cycles), but the cost to treat the same patient with H.P. Acthar Gel would be almost $700,000 (approximately 30 treatment cycles). As an example, at the Regional Sales Meetings on March 7th-8th in 2013, held in New Brunswick, New Jersey Blainy Creasy, the region's new Medical Science Liaison (MSL) gave a scientific talk about Acthar and its new mechanism of action (MOA) and how they intend to position it in the physician's offices. Stacy Clancy said that "*even though we sell 5 day, the docs are finding out that it is not working and some patients need another vial."*
>
> Plainly, promoting a five-day course of treatment with H.P. Acthar Gel inured to the patient's financial detriment and, more importantly, to the detriment of the patient's health and well-being. Questcor promoted the five-day treatment cycle in order to get both the physician and the patient "hooked" on the substantially more expensive H.P. Acthar Gel in lieu of Solu medrol [sic].

Strunck & Pratta Complaint at ¶¶ 146-150 at Ex. A.

Mallinckrodt Uses KOLs to Create Biased Clinical Data to Deceive Patients and TPPs, and to Cultivate High Acthar Prescribers as "Spokes-Doctors".

271. In view of the extremely limited clinical data that existed at the time of Acthar's approval in 1952, and since that time, Mallinckrodt has been forced to try to create data to support its false and misleading marketing effort about Acthar's "value" to treat disease beyond the narrow indications on its label.

272. Mallinckrodt cultivated so-called "Key Opinion Leaders" or "KOL's" create such data, and then disseminated such data to other doctors through their highly-compensated spokes-doctors.

273. As ProPublica has reported, and as demonstrated below by a few examples, dozens of high prescribers of Acthar have been cultivated as spokes-doctors and paid tens of

thousands of dollars for their work on behalf of Mallinckrodt in this regard.

274. These KOLs are paid by Mallinckrodt to cultivate a narrow group of high prescribers of Acthar, some of whom are also engaged by Mallinckrodt to generate clinical data based on their own patient populations to support Acthar's off-label uses and doses, without FDA oversight, input or scrutiny. The company then widely disseminates the results of such anecdotal studies as part of its vast marketing campaign to convince doctors that Acthar is safe and effective for unapproved uses.

275. As similarly alleged in the opioid litigation, in which Mallinckrodt has been sued as a defendant in MDL 2804 (pending in an Ohio Federal District Court) and in state courts throughout the country, including New Jersey, Mallinckrodt cultivated a select circle of doctors who were chosen and sponsored for their pro-Acthar messages in order to create "the grave misperception science and legitimate medical professionals favored the wider and broader use" of Acthar. These KOLs were used to present the appearance that unbiased and reliable medical research supporting the broad use of Acthar for neurology, nephrology and rheumatology had been conducted and was being reported on by independent professionals. See In re: National Prescription Opiate Litigation, Case No. 1:17-md-02804-DAP, N.D.Ohio, Doc. No. 1025 (Report and Recommendation dated October 5, 2018) at 6-7.

276. The publications of many of these physicians, including those of Dr. James A. Tumlin of Tennessee described below, were funded by Mallinckrodt as they supported the position that Acthar for broad use in neurology, nephrology and rheumatology was appropriate, all the while knowing these statements were false, misleading and deceptive.

277. Mallinckrodt utilized KOLs, like Dr. Tumlin, to develop "open label" clinical data to support Mallinckrodt's promotion of Acthar for new indications in nephrology, neurology and

rheumatology.

278. "Open label" clinical trials, unlike the FDA-approved trials described above, do not attempt to disguise the drug being studied, meaning that no standard treatment or placebo is utilized. This leans towards bias, as both the patient and the physician are aware of which groups are receiving what type of treatment. The results are thus unreliable.

279. In NS, for instance, Mallinckrodt was aware as early as 2009 that doctors were nearly unanimous in their expression of a need for clinical data to support the efficiency and safety of Acthar in NS, as well as the need for clarification on the appropriate dosing regimen. Working with KOLs who expressed interest in generating such data became a major focus for Mallinckrodt MSLs in 2009 and beyond.

JAMA Study of Mallinckrodt KOLs, and Connection Between Kickbacks Payments and Higher Acthar Prescriptions.

280. In June of 2018, a team of researchers and concerned clinicians used Medicare and Medicaid data to investigate the frequency of use and overall expense of Acthar. To characterize payments from Mallinckrodt to physicians who prescribe Acthar, these researchers and clinicians conducted a cross-sectional analysis of data from CMS, including the Medicare Part D Public Use Files. Focusing on 2015, the researchers used the database to identify physicians, and their specialties, who prescribed Acthar more than 10 times that year, characterizing them as "frequent prescribers."

281. Their study, published in JAMA Network Open, found that in 2015 only 300 providers wrote more than 10 prescriptions for Acthar. Of those 300 prescribing providers of Acthar, 235 of them were rheumatologists, neurologists, or nephrologists.

282. Further, among those 235 rheumatologists, nephrologists and neurologists who issued more than 10 prescriptions for Acthar in 2015, 88% (207/235) received payments from

Mallinckrodt – with more than 20% of those frequent prescribers receiving more than $10,000 – despite Acthar's considerable cost and the dearth of evidence to support its use.

283. Some physicians prescribing Acthar were paid as much as $56,000-$138,000 by Mallinckrodt for activities related to Acthar, making such payments equivalent to the salary of full-time employees of Mallinckrodt.

284. Indeed, as noted by one of the researchers and clinicians in the JAMA study, Dr. Daniel M. Hartung, "[e]xpensive therapies with uncertain or insufficient evidence supporting their use should be particularly scrutinized." He further noted that, "[t]he continued growth in corticotropin [Acthar] use is peculiar given its very high cost, widespread negative media coverage, and notable lack of evidence supporting its use over lower-cost synthetic corticosteroids. Our experience suggests aggressive marketing of the drug partly accounts for increasing use."

285. The JAMA study also noted an association between providers who received higher compensation and their writing more Acthar prescriptions—and the Acthar prescriptions written by these frequent prescribers accounted for $200 million in Medicare spending during the period that the study examined.

286. Indeed, this study also found that from 2011 to 2015, spending on Acthar increased ten-fold, totaling more than $1.3 billion for just several thousand Medicare patients. Upon information and belief, and given the continued marketing of Acthar by Mallinckrodt pursuant to the marketing scheme alleged by the Qui Tam Relators, those numbers have increased since 2015.

287. The conclusion of the JAMA study was that most nephrologists, neurologists, and rheumatologists who frequently prescribe Acthar received Acthar-related payments from

Mallinckrodt, suggesting that financial conflicts of interest may be driving the prescription and use of Acthar. Indeed, as noted by Dr. Hartung, "we observed a positive association between the amount of money paid to these prescribers, their prescribing intensity, and corticotropin [Acthar] expenditures in the Medicare program with a return on investment for Mallinckrodt of about 5:1."

288. Consistent with the JAMA study's conclusions, in October of 2014, Mallinckrodt had a briefing with its investors. At that briefing, Dr. Gary Phillips, the Senior Vice President, and President of Mallinckrodt's Autoimmune and Rare Disease Business, pledged, "[t]he one thing that you can be sure of is that the awareness and the evidence of the product will just expand dramatically over the next year."

289. Dr. Phillips presented PowerPoint slides detailing the company's strategy, including the need to get Acthar to its "underserved patient population" in rheumatology, pulmonology, ophthalmology, dermatology and kidney disease.

290. One graphic showed 9,000 patients were currently being treated with Acthar and that 300,000 people had "addressable but currently untreated" conditions. The slide also noted a total of 4 million Americans suffered from "Acthar indicated conditions."

291. The aggressive marketing push outlined by Mallinckrodt executives in that October 2014 investor meeting appears to have paid off: Medicare spent more than $600 million on more than 12,000 Acthar claims in 2016 – more than double the numbers from 2013, the year before Mallinckrodt's purchase of Questcor. Many of those prescriptions were made by rheumatologists, nephrologists, and neurologists – the very type of doctors Mallinckrodt executives said they planned to target in October 2014 to capture the "underserved patient population."

292. Few medical providers have come forth to blow the whistle on Mallinckrodt's tactics. One brave doctor, Dr. Megan Clowse of the Duke University School of Medicine, wrote last year that "[w]e also know from personal experience that Acthar's manufacturer is actively looking for clinical researchers open to perform more, small, open-label, nonrandomized trials of their drugs." In other words, even doctors not receptive to Mallinckrodt's marketing scheme are approached. Discovery of Mallinckrodt's records will enable Plaintiff and the Class to ferret out the chaff from the wheat, the ethical doctors from the spokes-doctors.

293. One such spokes-doctor, Dr. William Shaffer, a neurologist in Greeley, Colorado, was the highest prescriber of Acthar in 2012. He wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare $4,000,000.

294. Dr. Shaffer has been paid handsomely by Mallinckrodt for his loyalty to the company. The very next year, Dr. Shaffer was rewarded by being engaged by Mallinckrodt to speak as a KOL on multiple occasions, in multiple places, as part of all-expense paid trips sponsored by the company. For instance, he was flown to the east coast to conduct four speaking engagements with dozens of the doctors over the course of two days, January 24-25, 2013. He spoke in Reston and Falls Church, Virginia, and then Bethesda, Maryland.

295. But Dr. Shaffer was far from alone. He is just one of dozens of highly-compensated Mallinckrodt spokes-doctors, all important spokes in the wheel of Mallinckrodt's RICO conspiracy, as they are all connected to Mallinckrodt's self-described "HUB" and all profit as integral "spokes" in Mallinckrodt's marketing and sales scheme.

Leading "KOLs" for Mallinckrodt Promote for "New Indications" through a Scheme of "White Coat Marketing".

296. Mallinckrodt sought help in effectuating their scheme and conspiracy by seeking KOLs in the medical fields where Acthar was not the preferred course of treatment. Indeed,

Acthar was not approved by the FDA for the long-term treatment of any disease; instead, Acthar has had a narrow indication since 1952 for the treatment of only acute exacerbations of disease and flare-ups.

297. As Express Scripts' 2018 Prior Authorization Policy acknowledged, "data and guidelines do not suggest that Acthar has a substantial role in therapy" for most of the diseases for which Mallinckrodt promotes and sells Acthar. Instead, Express Scripts found in late 2017, as the FDA found in 2010, that "[f]urther data are needed before use in other areas [beyond IS and MS] can be recommended." *Id.* at 4 (brackets added).

298. To overcome this lack of data to support to use of Acthar to treat "new indications", and to support its off-label marketing effort, Mallinckrodt engaged KOLs strategically situated throughout the country, initially to determine whether there was a viable potential market for Acthar with neurologists, nephrologists and rheumatologists.

299. In order to cultivate KOLs for its white coat marketing scheme, Mallinckrodt directed its sales force call on select neurologists, nephrologists and rheumatologists to discuss the treatment of new indications of disease with leading practitioners in these fields, and to begin developing and sharing the data on treatment with Acthar.

300. Mallinckrodt then began "[w]orking with KOLs who have expressed interest in generating such data" to support the off-label use of Acthar to treat such "new indications". This became a "major focus" for Mallinckrodt after it acquired Questcor.

301. This new marketing initiative into off-label promotion of Acthar for "new indications" was made possible by the "success of the new Acthar pricing strategy" by which "significant funds [were] now available for the first time to support Acthar-related research" by paying "KOLs to explore areas of mutual research interest." *Id.* In other words, the profits

realized by the implementation of the "new strategy" in 2007 for IS treatments made it possible for Mallinckrodt to pay doctors to serve as KOLs as part of the Mallinckrodt white coat marketing strategy into rheumatology, nephrology and other areas.

302. The practice of "white coat marketing" was identified by the Office of Inspector General (OIG) of the federal government as a potential area of fraud and abuse as early as 1991. See, e.g., OIG Advisory Opinion No. 11-08, issued June 12, 2011, at 6 (citing 56 Fed. Reg. 35952, 35974 (July 29, 1991)). As described in Advisory Opinion No. 11-08:

> The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity – a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services – especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

Mallinckrodt KOLs Working for Mallinckrodt as Spokes-Doctors in New Jersey and Throughout the Country.

303. While it is impossible without the benefit of discovery to identify and describe the full nature and extent of Mallinckrodt's unlawful white coat marketing scheme for the off-label promotion of Acthar – as only discovery will reveal the facts that lie within Mallinckrodt's exclusive custody and control – specific examples demonstrate that the scheme was widespread in New Jersey and elsewhere.

a. Dr. David R. Mandel in Chardon, Ohio

304. Dr. David R. Mandel ("Dr. Mandel"), is a rheumatologist with offices located at 320 Center Street, Chardon, Ohio.

305. Public reports reveal that Dr. Mandel was regarded as a top prescriber of Acthar

making up 1% of all prescriptions with 14 patients receiving Acthar.

306. According to the website sponsored by Propublica,9 Mallinckrodt claims Dr. Mandel was only paid the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country:

Aug. 2013 - Dec. 2013	$16,653
Jan. 2014 - Dec. 2014	$3,077
Jan. 2015 – Dec. 2015	$3,032
Jan. 2016 – Dec. 2016	$126

307. However, in 2014, Dr. Mandel pled guilty and was sentenced to probation and paid $650,000 for causing the shipment of "misbranded" drugs.

308. Mallinckrodt has been sued by a former employee, Barry Franks. In Franks' Complaint, he details the unlawful conduct of Dr. Mandel, along with another Mallinckrodt sales representative, identified as "Smith". It is believed and therefore averred that "Smith" is actually Christopher Sender, the Mallinckrodt sales manager in charge of the Ohio area where Dr. Mandel practices.

309. As a highly compensated KOL and spokes-doctor for Mallinckrodt, Dr. Mandel actively promoted the sale of Acthar to patients and TPPs for unapproved uses and doses in order to get TPPs, like Plaintiff and the Class, to pay for Acthar at inflated prices. Specifically, Dr.

[9] *See* https://projects.propublica.org/docdollars/ According to Propublica, "[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016."

Mandel promoted the sale of Acthar for RA.

310. In promoting Acthar for unapproved uses and doses in the treatment of RA, Dr. Mandel misrepresented and deceived patients and payors about the Acthar MOA and the limited FDA approval.

311. Dr. Mandel specifically wrote to payors, after his initial prescriptions for Acthar were denied due to the prior authorization TPPs had placed on Acthar to prevent high payments for specialty drugs, especially for off label indications. Working with Mallinckrodt's HUB, UBC, however, Dr. Mandel sent letters appealing the TPP's denial decisions. Such letters were sent to UBC, to be used with TPP's, through use of the mail, including email, and wires. They contained false and misleading statements about the limited FDA approval of Acthar and its purported MOA.

312. Specifically, as to the FDA approval, Dr. Mandel would write to TPPs that Acthar was approved for specific RA indications, when it was not. As for the Acthar MOA, Dr. Mandel would write to TPPs misrepresenting that the Acthar MOs was known, when it was not. Indeed, he would provide lengthy explanations about the Acthar MOA, which explanations were not based upon any FDA approval or any FDA approved clinical studies.

313. The letters sent and other communications had between Dr. Mandel and TPPs in order to appeal the denial of Acthar were vetted by and shared with Mallinckrodt and UBC. Mallinckrodt and UBC were fully aware of Dr. Mandel's misrepresentations, and yet took no steps to stop or correct them, to the detriment of the TPPs who paid for the Acthar based upon such misrepresentations. Instead, Mallinckrodt rewarded Dr. Mandel with increasing KOL speaking engagements, for which he was well compensated.

314. Based upon the JAMA study and other evidence of Mallinckrodt's KOL program

for Acthar, including the above-described example of Dr. Mandel for which specific evidence is available, it is averred that other KOLs conducted themselves in the same manner. That is, Mallinckrodt-paid KOLs misrepresented and deceived TPPs about the MOA for Acthar and the limits of its FDA approval, in order to get TPPs to pay for Acthar for unapproved uses and doses. These false and misleading communications were routed to TPPs through UBC via facsimile.

315. Plaintiff and the Class were harmed by such conduct, either directly through the promotional effort of Mallinckrodt KOLs and MSLs, or indirectly through their intercession in the care of beneficiaries of Plaintiff and the Class through the ASAP program and otherwise.

316. Plaintiff and other clients of the Plaintiff's counsel, along with unnamed members of the Class paid the inflated prices for Acthar for indications in MS, NS, SLE and RA pursuant to the fraudulent pricing, marketing and sales scheme alleged.

b. Dr. James Tumlin in Chattanooga, Tennessee and Acument's Inflated Payments for Acthar

317. In a related case filed in Tennessee state court by the same undersigned Plaintiff's counsel, the plaintiff there, Acument Global Technologies, Inc. ("Acument") has specifically pled that Mallinckrodt hired Dr. James A. Tumlin, M.D. ("Dr. Tumlin") as a leading KOL to develop supporting data using his existing patients as test subjects in a non-FDA-approved, open label clinical study.

318. Mallinckrodt also paid Dr. Tumlin to travel the country, instructing other doctors on the unapproved uses of Acthar for nephrology and soliciting such doctors to become KOLs for Mallinckrodt.

319. Mallinckrodt has paid Dr. Tumlin handsomely for such work on behalf of the company. He has been paid hundreds of thousands of dollars.

320. Dr. Tumlin is a physician who specializes in nephrology and is associated with

Nephrology Associates of Chattanooga located at 2300 E. 3rd Street, Chattanooga, Tennessee. He is founder and medical director of Southeast Renal Research Institute (SERRI) since 2005. The institute was brought to Chattanooga in 2008 and merged with Nephrology Associates' Research Department.

321. As with its other KOLs, Mallinckrodt contracted with Dr. Tumlin to conduct clinical studies of his patients using Acthar to treat their NS. This engagement was not to conduct any FDA-approved clinical study. Instead, it was intended by Mallinckrodt to pay Dr. Tumlin to conduct clinical studies of his own patients by prescribing Acthar to them for unapproved uses and doses to treat their nephrotic syndrome in order to learn about the effects of Acthar on their disease and assist Mallinckrodt in developing anecdotal clinical data with which to promote Acthar's use to other nephrologists. It is believed that one such patient was a beneficiary of Acument.

322. The 2009 contracted study was titled "A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects with Persistent Proteinuria and Nephrotic Syndrome Due to Idiopathic Membranous Nephropathy (iMN)" (hereinafter, "Tumlin 2009 Randomized Study"). It is believed and therefore averred that Dr. Tumlin "enrolled" 15 patients for this study. While Acument's beneficiary had iMN, it is unknown whether Acument's beneficiary was included among the 15 patients Dr. Tumlin treated with Acthar as part of this contracted study. Only discovery in these cases will reveal the truth.

323. However, it is known Dr. Tumlin did not charge either the beneficiary or Acument for the Acthar he prescribed in 2011. Instead, it is believed and therefore averred that Mallinckrodt provided the drug for free in order that Dr. Tumlin could develop data to assist in

its marketing and sales of Acthar to other nephrologists.

324. Dr. Tumlin's work on behalf of Mallinckrodt became a centerpiece of its marketing plan for nephrologists, not just in Tennessee, where Dr. Tumlin's practice, Southeast Renal Research Institute, was located in Chattanooga, but throughout the country, including New Jersey.

325. As with other KOLs, Dr. Tumlin travelled across the country on all expenses paid trips funded by Mallinckrodt to promote the use of Acthar for NS and other disease states for which there were no clinical studies to support the treatment. Instead, Dr. Tumlin cited to other doctors his own anecdotal experience with his patients, about which he published in two papers, the Tumlin 2001 Study and the Tumlin 2013 Pilot Study.

326. While it is not yet known the total dollars Mallinckrodt paid Dr. Tumlin for these two "studies" which led to published articles, those monies were only part of Dr. Tumlin's compensation for working for Mallinckrodt.

327. For instance, Dr. Tumlin conducted a third study titled "Safety and Efficacy of Acthar Gel on Albuminuria and Urinary Transforming Growth Factor Excretion in Type II Insulin Requiring Diabetics with Nephrotic Range Proteinuria: A Pilot Study". Mallinckrodt paid Dr. Tumlin for that study.

328. In its prior authorization update released in 2018 – 9 years after Mallinckrodt began white coat marketing of Acthar through KOLs like Drs. Mandel and Tumlin– Express Scripts stated that Acthar should not have been "recommended for approval" by any doctor, including Dr. Tumlin, for treatment of iMN in patients.

329. In fact, Express Scripts cited Dr. Tumlin's 2 published papers sponsored and paid for by Mallinckrodt: the Tumlin 2011 Study and the Tumlin 2013 Pilot Study,10 in concluding that "very limited data in nephrotic syndrome have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephropathy (iMN)…".

330. Mallinckrodt MSLs and sales representatives used Dr. Tumlin's open label studies to promote the sale of Acthar for off-label uses and doses. Similarly, UBC was trained with Dr. Tumlin's studies and used them in discussing the use of Acthar for unapproved uses and doses with patients, providers and TPPs.

331. According to the website sponsored by Propublica,11 Dr. Tumlin was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country, apart from the monies he has earned conducting "clinical studies" of his patients:

Aug. 2013 - Dec. 2013	$15,318
Jan. 2014 - Dec. 2014	$27,733
Jan. 2015 – Dec. 2015	$28,839
Jan. 2016 – Dec. 2016	$50,840

[10] Bomback AS, Tumlin JA, Baranaski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Des Devel Ther*. 2011; 5:147-153 ("Tumlin 2011 Study").

[11] *See* https://projects.propublica.org/docdollars/ According to Propublica, "[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016."

332. On multiple occasions, Dr. Tumlin was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious effort to overpay Dr. Tumlin for his "consulting" activities.

333. For instance, on May 23, 2016, Propublica reports that Dr. Tumlin received two payments from Mallinckrodt for "promotional speaking" in the amount of $3,400 each. He also received two equal payments of $2,050 for "promotional speaking" July 2, 2015.

334. On June 17, 2015, Mallinckrodt paid Dr. Tumlin the following sums for "travel and lodging" for just one day: $537, $529, $393, $393, $276, $87, $50, $50, $30, $30 and $22.

335. Based on the Propublica information, it is believed that Dr. Tumlin travelled the country for Mallinckrodt to promote Acthar use in nephrology. Mallinckrodt paid with substantial "honoraria" paid, totaling up to $5,000 at time, for his time and effort.

336. The specific dates, locations and payments relating to these Dr. Tumlin's consulting for Mallinckrodt as a leading KOL lies within the exclusive control of Mallinckrodt and Dr. Tumlin, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

c. Dr. Gary Clauser in Allentown, Pennsylvania And IUOE Local 542's Inflated Payments for Acthar

337. Gary Clauser, M.D. is a board-certified neurology specialist in the Lehigh Valley Physician Group (LVPG) with offices located at 1250 S. Cedar Crest Boulevard, Suite 405, Allentown, Pennsylvania. LVPG has additional offices located in Bethlehem and Palmer Township, Pennsylvania.

338. In July 2011, Dr. Clauser treated a patient covered by the International Union of Operating Engineers Local 542 ("IUOE Local 542") located in Fort Washington, Pennsylvania.

IUOE Local 542 has sued Mallinckrodt individually in Pennsylvania state court. Earlier this year, the Court of Common Pleas of Montgomery County denied Mallinckrodt's Preliminary Objections seeking to have the case dismissed. Since that time, the case has been proceeding through discovery.

339. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Art Veno, Dr. Clauser utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 on behalf of Mallinckrodt at the inflated AWP price set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiary were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP program.

340. Dr. Clauser has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy allege herein by Dr. Clauser's role as a highly paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Clauser has treated patients with Acthar on at least the following dates for the identified conditions: June 9, 2014 (MS); September 10, 2014 (MS); September 12, 2014 (MS); October 9, 2014 (MS); October 15, 2014 (MS); February 24, 2015 (MS); April 20, 2015 (MS); June 3, 2015 (MS); and June 8, 2015 (MS).

341. Dr. Clauser prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt by submitting the prescription through IUOE Local 542's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

342. Specifically, Dr. Clauser prescribed an unapproved 5-day dose of Acthar to treat a patient with MS, who was also a beneficiary of IUOE Local 542. Dr. Clauser filled out an

Acthar Start Form on June 29, 2011, listing "80 units/day x 5 days" for MS, and faxed the form to UBC to obtain coverage and payment from IUOE Local 542, which it did.

343. Dr. Clauser held a meeting with Mallinckrodt in his office in Allentown on Tuesday, January 8, 2013. Also in attendance were his employees, nurse practitioner Jean Bakke-Cain and registered nurse Grace Connelly.

344. The meeting was arranged by Mallinckrodt's sales representative for the Lehigh Valley, Art Veno. Also invited to attend was one of Mallinckrodt's top 10 KOLs in the country, Dr. Ruwani Gunawardane, a neurologist from Fulton, Maryland. While it is unknown what was said at the meeting, based on the express goals of the KOL program, it is likely that Dr. Gunawardane was brought from Maryland to Allentown to further train Dr. Clauser in the "art" of being a top Mallinckrodt KOL and spokes-doctor. It is believed and therefore averred Dr. Gunawardane also taught Dr. Clauser about the off-label uses and doses of Acthar for the treatment of his patients, including for the treatment of MS. Dr. Gunawardane specifically thanked Dr. Clauser and his staff at Lehigh Neurology about "perspectives on MS relapses and Acthar."

345. Only discovery will reveal if Dr. Gunawardane has been paid more than a consulting fee, honoraria and travel expenses, such as whether she has been paid additional monies based on the Acthar sales generated by Dr. Clauser in the wake of her visit to him. Such a "pyramid scheme" would perhaps explain how Dr. Gunawardane has been able to generate more than $100,000 a year working for Mallinckrodt as a KOL, in addition to maintaining a healthcare practice in Maryland.

346. According to ProPublica, Dr. Gunawardane has been paid a staggering $1,111,326 as a paid consultant to drug companies, $332,000 of which was paid by

Mallinckrodt. She is among the top eight largest prescribers of Acthar in the country, and is among the highest paid of Mallinckrodt's KOLs.

347. Specifically, according to CNN, Dr. Gunawardane "received 502 payments worth $332,393.36 -- nearly half was compensation for services, about a third was honoraria, about a sixth was for travel and lodging, and the rest was for consulting, education and food and beverage. Gunawardane filed 38 claims resulting in $1,329,002.84 in Medicare coverage."12 Dr. Gunawardane declined to comment when confronted by CNN. *Id.*

348. Dr. Clauser became a Mallinckrodt "spokes-doctor" and KOL after the January 8, 2013 meeting with Mallinckrodt and Dr. Gunawardane. Dr. Clauser has been a highly KOL for Mallinckrodt for years.

349. According to Propublica, which has only published data since the second half of 2013, Dr. Clauser was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors throughout Pennsylvania and New Jersey:

Aug. 2013 - Dec. 2013	$9,124
Jan. 2014 - Dec. 2014	$26,959
Jan. 2015 – Dec. 2015	$8,727
Jan. 2016 – Nov. 2016	$18,286

350. In the first half of 2013 alone, since the meeting with Dr. Gunawardane, Dr. Clauser served as a Mallinckrodt KOL on at least the following occasions in the following

[12] https://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html

places:

January 18, 2013	Wilkes Barre, PA
March 22, 2013	East Norriton, PA
April 16, 2013	**Bridgewater, NJ**
April 18, 2013	Sellersville, PA
April 29, 2013	Manhattan, NY
May 14, 2013	Brooklyn, NY
May 21, 2013	King of Prussia, PA
June 26, 2013	Brooklyn, NY
August 1, 2013	Center Valley, PA

351. On multiple occasions, Dr. Clauser was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious kickback to the doctor.

352. Based on the Propublica information, Mallinckrodt paid Dr. Clauser substantial "honoraria" and "consulting" fees, totaling up to at least $59,423, for his time and effort.

353. The specific dates, locations and payments relating to Dr. Clauser's consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Clauser, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

Mallinckrodt's and UBC's False and Misleading Marketing About the "Mechanisms of Action" for Acthar, in Promoting the Drug for a Wide Range of Unapproved Uses and Doses, Putting Patients at Substantial Risk.

354. In addition to the lack of proven safety or efficacy for the host of uses and doses that Mallinckrodt and UBC promote Acthar in neurology, nephrology and rheumatology, and the dangerousness of Acthar for such unapproved uses and doses, Mallinckrodt and UBC do not know, and have not known since it acquired the product was acquired by Mallinckrodt in 2001, the exact "mechanism of action" ("MOA") for Acthar. In other words, neither Mallinckrodt nor UBC know how Acthar works, even to treat the disease states for which it has been approved.

355. In view of this lack of understanding of the MOA for Acthar, the FDA has

mandated the following lines be included on the Acthar label:

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown.

356. In 2010, in response to Mallinckrodt's request for approval of the IS indication for Acthar, the FDA expressly found that "the exact mechanism of action for specific indications, such as the treatment of infantile spasms, is not known." DDMAC Memo at 1 (emphasis added). The FDA made such finding in part due to the fact that the original FDA approval in 1952 was based upon limited clinical evaluation of patients, not any current FDA-approved clinical study standards.

357. Despite these unambiguous findings by the FDA, both Mallinckrodt and UBC misrepresent and deceive providers, patients and TPPs into prescribing, taking and paying for Acthar, respectively, for unapproved uses and doses. Mallinckrodt has repeatedly and consistently misrepresented to the public the "value" of Acthar for specific indications, including the rheumatoid disorder for which the Local 322 beneficiary was prescribed Acthar. UBC coordinates the Acthar prescription from inception to payment, answering all questions posed by providers, patients and TPPs, including questions about the MOA for Acthar and whether it works for the prescribed indication.

358. Internally, Mallinckrodt concedes that, even for IS, the "[e]xact mechanisms of action of ACTH in the treatment of infantile spasms are not fully understood."

359. Publically, however, Mallinckrodt has falsely and misleadingly promoted the sale of Acthar for the long-term treatment of MS, NS, SLE and RA, despite its limited approval for only acute exacerbations of disease.

360. Indeed, it has been part of Mallinckrodt's long-term business strategy since 2007 to promote the administration of Acthar as a maintenance medication for all indications where it is approved only for the treatment of acute episodes or exacerbations of disease.

361. Prior to the launch of the new strategy in 2007, Mallinckrodt's top executives, at best, had a "rudimentary understanding" of the Acthar MOA. Nevertheless, Mallinckrodt's top executives have routinely misrepresented the value of Acthar for the treatment of specific unapproved indications, despite the FDA's express finding that the MOA is not known.

362. For instance, Mallinckrodt's former COO Steve Carrt has admitted under oath before the FTC that "in 2006, we had only a very rudimentary understanding of either Acthar or synthetic ACTH, understanding both products evolved considerably between 2006 and the present time."

363. Since that time, Mallinckrodt's knowledge of the MOA for Acthar has remained "rudimentary" as to all the disease states for which Mallinckrodt markets and sells Acthar, including and especially those for which there has been no FDA approval.

364. This lack of understanding has not impacted Mallinckrodt's training of UBC's RS's who alone interface with the providers, patients and payors, passing on Mallinckrodt's misleading and deceptive messages about Acthar's purported uses and benefits.

365. In August 2011, when asked directly by investors about the Acthar MOA, Questcor CEO Don Bailey claimed publicly that while "Acthar is an extraction of porcine pituitaries", "it's an undisclosed composition, so that's a trade secret." In other words, he misled the public that the company would not disclose the "undisclosed composition" of Acthar, when in actuality it was unknown. Bailey further claimed falsely that it is a barrier to entry for

competitors to enter the market for ACTH drugs because "there are probably multiple active ingredients" in Acthar, and "there are multiple peptides within Acthar, and they're undisclosed." (emphasis supplied).

366. Claiming that the MOA for Acthar is "undisclosed" blatantly misrepresents that it is somehow known by Mallinckrodt, but is not being disclosed by the company because it is supposedly a "trade secret". It can only be a trade secret if it is known.

367. During that same investor conference call, CEO Bailey was questioned about the MOA for Acthar, and stated "there is actually a fair amount of confusion about the mechanism of action here." He then passed the question to Christine Clemson, Mallinckrodt MSL. Clemson falsely claimed, "[w]e now know [about Acthar's] effects in, say, MS are really relevant to its direct effect on the immune system. …So that's really the primary, direct effect of Acthar that I discuss in an MS's office. This is new information…." *Id.* (emphasis supplied).

368. As discussed below, in the case of the beneficiaries of Plumbers Local 322, Mallinckrodt's and UBC's direct misrepresentations about the purported MOA of Acthar in the treatment of MS exacerbations, through their MSLs/sales representatives and RSs, respectively, led to those beneficiaries receiving unapproved, off label, 5-day dosing of Acthar, for which Plumbers Local 322 was forced to pay inflated Acthar prices.

369. Both Mallinckrodt and UBC have encouraged KOLs to speak to patients and TPPs about the MOA of Acthar in order to get them to agree to prescriptions of Acthar for unapproved uses and doses.

370. For instance, in the case of Dr. Mandel, when one of his patients was denied coverage for Acthar on February 27, 2014, he faxed UBC a letter to be sued with the "Clinical Appeals Department" of Express Scripts. In the letter, Dr. Mandel falsely and misleading

requested coverage for RA – not an RA exacerbation. He claimed "medical necessity" and stated "H.P. Acthar Gel is FDA approved therapy for Rheumatoid Arthritis". He then stated "Acthar has a very unique mechanism of action", and proceeded to try to explain what the FDA has mandated on the Acthar label is "unknown." This letter was used by UBC and Mallinckrodt to get coverage for the patient for RA, an unapproved use.

371. Since the time of the adoption of the new strategy in 2007, Mallinckrodt has been spending money in research to try to discover and understand the MOA of Acthar, all the while promoting the drug as safe and effective for the treatment of diseases for which it is has not been approved and for which its efficacy remains unknown, especially at the doses Defendants promote.

372. Despite its longstanding "rudimentary understanding" of the Acthar MOA, Mallinckrodt and UBC have continued to aggressively promote Acthar as both safe and effective, and valuable, for the treatment of a host of diseases, including as long-term, maintenance medication for MS, NS, SLE and RA.

373. Due to their aggressive marketing, Mallinckrodt sales representatives and MSLs, and UBC "Reimbursement Specialists" or "RSs", are questioned most often by doctors about the efficacy of Acthar and its MOA. Mallinckrodt sales representatives and MSLs, and UBC's RSs, are trained to misrepresent the truth about Acthar's MOA and its limited efficacy, and to deceive providers, patients and TPPs about the limited benefits of Acthar.

374. Because it operates Mallinckrodt's HUB for the ASAP program, these same questions are most often posed to UBC. These people are known as "Reimbursement Specialists" or "RSs", and they are assigned to each patient at the time of the Acthar Start Form submission or initial call to UBC. The RS then follows the patient's case until delivery of Acthar

and payment by the TPP.

375. The UBC RS directly communicates the false and misleading messages of Mallinckrodt about Acthar, its uses and doses, including off label uses and doses, its supposed benefits in relation to other treatments, and its price and value for the price charged. They do this because they are directly trained by Mallinckrodt MSLs and other employees sent by Mallinckrodt to train all new RSs, and to update the training of existing RSs. UBC RSs are not clinical pharmacists; they have no medical degrees. They are specialists in prescription drug reimbursement. In other words, they specialize in finding ways to get high priced drugs like Acthar paid for by TPPs like Local 322.

376. Neither Mallinckrodt's nor UBC's marketing and promotion of Acthar described in this Complaint has been submitted to, reviewed by, or approved by the FDA, as required.

377. In light of that, as discussed below, the DOJ has chosen to intervene in the lawsuit brought by Qui Tam Relators Strunck, Pratta and Clark to advance the claims of these former Mallinckrodt employees challenging such marketing and sales scheme. *See generally*, *Strunck & Pratta* Complaint and U.S. Complaint filed in federal court.

Mallinckrodt Funds "Patient Assistance Programs" Run by UBC to Fund Patients Copays to Circumvent Patient Complaints and TPP Advance Awareness about Acthar's High Prices.

378. In the U.S. Complaint in Intervention, the government includes detailed allegations about Mallinckrodt's use and employment of free Acthar and copay assistance through a "scheme [that] allowed the Company to continually raise Acthar's price yet market it as 'free' to patients and doctors, shifting the drug's ever-increasing cost to Medicare." *Id.* at ¶ 2.

379. So too, such Marketing Scheme allowed Mallinckrodt, with UBC's direct assistance and intervention in running the Mallinckrodt "Patient Assistance Program" or "PAP",

to shift the high costs of Acthar to private payors, like Local 322 and the Class of TPPs and their beneficiaries.

380. As the government alleges, "Mallinckrodt [and UBC] knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations of multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt [and UBC] intended to overcome this difficulty and did so by making the drug 'free' to patients by subsidizing their Medicare copayments. By doing so, Mallinckrodt [and UBC] could maintain the high price of Acthar to maximize [their] own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it." *Id.* at ¶ 4 (brackets added).

381. "Mallinckrodt knew that paying copay subsidies to Medicare [and private] patients was illegal. To achieve the same end indirectly, Mallinckrodt paid copay subsidies through a foundation that Mallinckrodt used as a conduit to do so. At the foundation, call the Chronic Disease Fund (now d/b/a Good Days)(collectively "CDF"), Mallinckrodt designed the supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations' knowing that its money would be used on Acthar copays to the exclusion of other drugs. Mallinckrodt then sent Medicare [and private payor] patients to CDF in order to receive virtually guaranteed, Mallinckrodt-funded subsidies. The Company also obtained and used data about the number of patients at CDF, the subsidies paid to them, and the amount of money Mallinckrodt needed to pay to keep covering Acthar copays. Mallinckrodt financed the funds accordingly." *Id.* at ¶ 5 (brackets added).

382. "Mallinckrodt sent patients to CDF via the Company's 'reimbursement hub' [UBC] for Acthar, called the Acthar Support and Access Program ("ASAP"). Mallinckrodt

controlled ASAP, which included a call-center that received referrals for Acthar from physician offices and patients. Mallinckrodt's sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so the Company could track them. After a referral came in to ASAP, as discussed in more detail [herein], ASAP [via UBC] provided patients with an 'automatic offering' of copay assistance via CDF." *Id.* at ¶ 100 (brackets added).

383. Mallinckrodt set up a specific fund with CDF titled the "MS Acute Exacerbation Fund" for which Acthar was the only listed treatment, in order to ensure that all monies "donated" by Mallinckrodt were earmarked exclusively for patients receiving Acthar. Then, all the provider, working with UBC, need to do was to list the patient's indication as an "MS Exacerbation" in order to send the patient to CDF for copay assistance with their Acthar copay. The MS Acute Exacerbation Fund had at least twice the available benefit per patient than any other program offered by CDF – at least $8,000. That was likely to ensure that any copay up to 20% would be covered.

384. As the government alleges, "Mallinckrodt, via ASAP [and the UBC HUB], referred Acthar patients to the fund regardless of whether they were using the drug for an acute exacerbation or on a long-term basis. Internally, Mallinckrodt referred to this longer-term use of Acthar in MS patients as 'pulse maintenance' or 'pulse' therapy." *Id.* at ¶102 (brackets added).

THE QUI TAM WHISTLEBLOWER COMPLAINT AGAINST MALLINCKRODT

385. On April 30, 2019, CNN reported that the United States Department of Justice ("DOJ") had intervened in a false claims act action brought by two former employees of Mallinckrodt.

386. The intervention actually took place the month before, on March 6, 2019, but the case was sealed at the time. *See Plaintiff Under Seal v. Defendant Under Seal*, Civil Action No.

12-CV-0175-BMS, E.D.Pa., at Dkt. No. 55. The government's decision to intervene, a relatively rare occurrence, was done after the government conducted its own extensive investigation of the claims by the former employees and concluded that the allegations are credible.

387. The case, now known as *U.S. ex. Rel. Charles Strunck and Lisa Pratta*, was filed in 2012 by Charles Strunck, New York-based former Multiple Sclerosis ("MS") Sales Specialist for Questcor, and Lisa Pratta, a New Jersey-based Acthar neurology specialist for both Questcor and Mallinckrodt (collectively, the "Relators"). Strunck worked from September 2010 through August 2011, while Pratta worked from September 2010 through June 2017, when it is believed and therefore averred she was terminated by Mallinckrodt once it successfully move the Court in Philadelphia to reveal her identity.

388. A second case was filed by a third former Mallinckrodt employee, Scott Clark, alleging that "Mallinckrodt designed supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations', knowing its money would be used on Acthar copays to the exclusion of other drugs." *See* U.S. Complaint, Dkt No. 2:13-cv-01776-BMS (E.D.Pa.) (BMS) at Document No. 57 at ¶ 5. These programs were run by and through Cigna/Express Scripts UBC "hub".

389. As reported by CNN, and as averred in their Qui Tam Complaint, the Relators allege that Mallinckrodt has engaged in a long-standing scheme to bribe doctors to prescribe Acthar at the exorbitant, inflated prices detailed herein. They claim there was a "culture" at Mallinckrodt designed to sell Acthar at all costs, from lying to the FDA to offering bribes to doctors.

390. Importantly, Mallinckrodt has not denied the allegations. Instead, Mallinckrodt claims the conduct alleged is a "legacy matter" involving Questcor and its conduct prior to

Mallinckrodt's acquisition.

391. However, the facts concerning Relator Pratta demonstrate the unlawful conduct continued after Questcor merged with Mallinckrodt in 2014. Pratta has alleged in her complaint that the conduct continued. And it continued up through at least June of 2017, when Pratta is believed to have been fired as a result of her identity being revealed in the Qui Tam case.

392. In a conference call with investors held May 7, 2019, CEO Mark Trudeau publicly stated that the company has reserved for the settlement of the Relators' case and is actively pursuing settlement which he stated is "likely to resolve sooner than later".

393. The conduct alleged by Relators involved kickbacks to doctors in the form of free Acthar, as well as active concealment by Mallinckrodt of the conduct for years.

394. For this reason, Local 322 did not know and could not have known about such unlawful conduct until the earliest date of April 30, 2019. As a result, Plaintiff's claims stated herein premised upon the unlawful conduct revealed by the Relators' case are timely.

395. Plaintiff had no way of knowing that Mallinckrodt was paying doctors thousands of dollars to prescribe Acthar to their patients.

396. The kickback scheme involved the promotion of Acthar to treat disease states for which Acthar was not the "gold standard", as in the case of IS, and for treatments that were not covered by the Acthar label.

397. For instance, Acthar is approved to treat acute exacerbations of disease. But the scheme uncovered by Relators involved widespread promotion of Acthar for the long-term treatment of disease as a maintenance medication.

398. Further, the scheme uncovered that Mallinckrodt sales representatives and MSLs were trained to promote unapproved doses of Acthar. For instance, in the treatment of MS

exacerbations, Acthar is not approved by the FDA for 5-day dosing.

399. The conduct revealed by the Relators goes to the manner in which Mallinckrodt was able to convince doctors to prescribe the high-priced Acthar, after the Defendant' conspired and agreed to raise the prices and maintain the prices at artificial levels, and to promote the sale of Acthar to such high prices through highly paid KOLs. The conduct involved systematically promoting and marketing Acthar for unapproved, off-label uses and doses.

400. The scheme involved compensating sales representatives thousands of dollars to promote the sale of Acthar for unapproved uses and doses, to benefit Mallinckrodt and the sales reps. Sales representatives have been paid tens of thousands of dollars for such promotional efforts. As detailed in the Relators' Qui Tam Complaint, one sales representative was paid a $124,000 bonus in the second quarter of 2011, including $75,000 for just one month. Others received bonuses of $110,000 and $80,000 in the same period.

401. The compensation of sales reps was directly tied to sales growth, a growth that was possible by expanding the approved uses for Acthar which had a narrow, limited market of patients.

402. Mallinckrodt employed a team of MSLs, like Sagar Shah, who were directed by Nikki Mutschler to join with sales specialists, like Strunck and Pratta to promote the sale of Acthar for unapproved uses. The Relators have identified the sales representatives who detailed the doctors of patients covered by TPPS in this Class.

403. To hide the fact that the promotional effort was for unapproved, off-label uses, Mallinckrodt referred to such uses as "new indications."

404. The sales of Acthar for these "new indications" became a primary focus for Mallinckrodt, as it strived to grow its revenue to the more than $1 billion in sales it achieves each

year for Acthar alone.

405. Mallinckrodt achieved such exponential growth, despite the price increases detailed herein, by providing valuable remunerations to doctors to induce and encourage them to prescribe Acthar for unapproved uses and doses.

406. As the Relators' Qui Tam Complaint reveals, and as Local 322 alleges herein, Mallinckrodt engaged in such conduct in violation of the New Jersey Consumer Fraud laws by providing secret kickbacks to doctors throughout the country, including New Jersey, to get them to prescribe Acthar at exorbitant prices, which Local 322 has been forced to pay. That is why Plaintiff seeks declaratory and injunctive relief against Mallinckrodt to end such practices.

DEFENDANT LISA PRATTA, ACTHAR SPECIALIST IN SOUTH JERSEY, ENGAGES IN THE SAME UNLAWFUL CONDUCT AS THE CORPORATE DEFENDANTS, FOR FIVE YEARS PAST THE TIME SHE SUED MALLINCKRODT AS A SUPPOSED "WHISTLEBLOWER"

407. Lisa Pratta was an Acthar neurology specialist with Questcor and thereafter Mallinckrodt from September 2010 until June 2017.

408. In her Complaint, filed in 2012 while she was still employed by Questcor, Pratta charged her employer with all the following unlawful conduct:

a. Mallinckrodt engaged in a longstanding marketing scheme to promote the use of Acthar for unapproved uses at unproven (and potentially unsafe) doses, especially in the treatment of MS;

b. Mallinckrodt's MSLs were employed to provide kickback to doctors throughout New Jersey and elsewhere (dubbed "Key Opinion Leaders" or "KOLs") to get them to prescribe Acthar for unapproved uses and doses, and to get other doctors in New Jersey to do the same during company-sponsored dinners and outings organized by sales representatives, like Pratta;

c. Mallinckrodt engaged in a scheme to provide kickbacks through the use of patient assistance programs ("PAPs"), which were fully funded by Mallinckrodt as a means of ensuring that patients did not have to pay anything for Acthar in order that the government and third party payors, like Local 322, were forced to pay the vast majority of the inflated cost of the drug

409. Unlike her co-whistleblowers, Strunck and Clark – who chose to leave Questcor upon discovery its unlawful conduct and suing their former employer – Pratta chose to stay, despite her allegations of unlawful conduct. She stayed for an additional five (5) years, during which time she engaged in the very same unlawful conduct she was actively complaining about in Pennsylvania Federal Court, albeit as a "Jane Doe" plaintiff in an under seal complaint.

410. Questcor, then Mallinckrodt, divided the country into "regions", named the Central, Great Lakes, Midwest, New England, North Central, Big South, Mountain, Northwest, Southeast, Southwest, West, Atlantic and Northeast regions. New Jersey fell in the Northeast region, consisting of the following sales territories: Brooklyn, NY, Downstate NY, Long Island, Manhattan, North New Jersey and South New Jersey. Pratta was in charge of the South New Jersey territory in the Northeast region for the sales of Acthar to neurologists. Her counterpart in the North New Jersey territory, in 2012, when she sued, was Christine Traficant. Their region manager was named Ken Miller.

411. During her sales practices, with knowledge of her employers' illegal practices, Pratta utilized the Acthar referral form which was the document that initiated the sales of Acthar. The referral form then generated the Acthar Start Form which is referenced herein.

412. Pratta hosted dinners with KOLs about the unlawful promotion of Acthar for the treatment of MS at the unapproved, 5-day "pulse therapy" after she sued Questcor and up to the

time she was terminated by Mallinckrodt.

413. For example, Pratta routinely met with Acthar KOL Dr. Tommasina Papa-Rugino ("Papa-Rugino") of Manahawkin New Jersey about the unlawful promotion of Acthar for off-label, 5-day dosing. On Friday, February 15, 2013, Pratta hosted a dinner with Dr. Papa-Rugino at the restaurant called Villa Amalfi in Toms River, New Jersey. In attendance were New Jersey doctors, Dr. Stefali Grandlis, Dr. Paul Kostoulokes of Neptune New Jersey and Dr. Robert Terranova also of Manahawkin New Jersey. The topic of the meeting was "MS Relapses and the MCR System". It is believed and therefore averred that Pratta and Dr. Papa-Rugino promoted the use of Acthar for the unapproved 5-day dosing regimen during this dinner, in an effort to get these doctors to purchase Acthar from Defendants at the inflated prices, so that Pratta would get credit for the increased sales.

414. On Friday, March 15, 2013, Pratta hosted another dinner with Dr. Papa-Rugino at The Nizams in Egg Harbor Township, New Jersey. In attendance were New Jersey neurologists Dr. Syed Jaffery, Dr. Kanir Jaffery, and Dr. Robert J. Terrananm. The topic of the meeting again was "MS Relapses and the MCR System". It is believed and therefore averred that Pratta and Dr. Papa-Rugino promoted the use of Acthar for the unapproved 5-day dosing regimen during this dinner, in an effort to get these doctors to purchase Acthar from Defendants at the inflated prices, so that Pratt would get credit for the increased sales.

415. Pratta succeeded, and was handsomely rewarded by Mallinckrodt and Questcor. For instance, in 2012, Pratta was the highest paid sales neurology representative in New Jersey. In early 2012, her sales goal set by Questcor was 10 units of Acthar. She sold 9, and reached a 90% sales target, achieving a bonus payout of $4,250 in February 2012 alone. In contrast Christine Traficant was given a sale goal of 15, but sold only 4 units, achieving a bonus of only

$500.

416. It is no wonder Pratta chose to stay at Questcor, then Mallinckrodt. She was profiting from the very unlawful schemes that she complained about in her qui tam action against her current employer.

417. She even referred Acthar patients to Cigna/Express Scripts' UBC hub for patient co-pay assistance, as part of the scheme alleged by Relator Clark (but about which Pratta curiously says nothing in her separate qui tam complaint). For instance, on January 30, 2012, Pratta referred an as yet unidentified New Jersey-based MS patient of Dr. Papa-Rugino to UBC for referral to the Chronic Disease Fund for co-pay assistance to ensure that the TPP paid. That patient's Acthar prescription was processed and approved by Cigna/Express Scripts' Curascript, who shipped the free drug on February 9, 2012.

418. Just two years later, in 2014, Questcor began removing people from the speaker list based on the frequency of referrals made by the physician so that they can create "space." Pratta's South New Jersey Region Manager at the time, John Stabile, looked at how many referrals the speakers have written in the year and also how many times the doctor was used for Health Care Provider and Patient programs. As Pratt admits in her own complaint, Stabile asked Pratta directly if he could make Dr. Papa-Rugino inactive, because "'she has not put in many referrals this year" and not been used that much. *Strunck & Pratta* Complaint at ¶ 158.

CLASS ACTION ALLEGATIONS

419. Local 322 brings this action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and other similarly-situated persons and entities, and their beneficiaries, New Jersey Class of others similarly-situated in New Jersey in consisting of the following:

> All third-party payors and their beneficiaries (1) who are current citizens and residents of the State of New Jersey, and (2) who, for purposes other than resale, purchased or paid for Acthar from August 27, 2007 through the present. For purposes of the Class definition, individuals "purchase" Acthar if they paid all or part of the purchase price based on the AWP for Acthar.

420. Excluded from the above Class are: (a) Defendants and any entity in which and Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, (b) any co-conspirators with Defendants, and (c) any government payor, including Medicare, Medicaid and/or Tricare. Also excluded are any TPPs and/or their beneficiaries who are not current New Jersey citizens and residents, and beneficiaries who did not purchase, reimburse or pay for Acthar in New Jersey. All such non-New Jersey residents and non-New Jersey transactions for Acthar are expressly excluded from the Class and the Class claims in this case.

Numerosity

421. The proposed Class consists of thousands of private payors and their beneficiaries in the proposed Class located throughout New Jersey, based on the fact that Defendants have sold thousands of vials of Acthar in the state during the relevant time period of August 2007 through the present. Thus, the Class is so numerous that joinder of all of its members is impractical.

422. Despite the size of the Class, its members are easily identifiable and ascertainable, as each patient has been required by Mallinckrodt since 2007 to fill out an Acthar Start Form as part of the ASAP. The Cigna/Express Scripts Defendants have a database of names and addresses of each member of the putative class, along with the amount of Acthar they purchased and what they paid. Defendant Pratta knows the same information for all the doctors in her southern New Jersey territory she detailed during the period of her employment up through 2017.

As a result, the records needed to identify the members of the Class, and the payments made by TPPs and their beneficiaries in the Class, are in the hands of the Defendants and/or its agents.

Typicality

423. Local 322's claims are typical of the claims of the Class, in that the representative Plaintiff is an entity who, like other Class Members, paid for Acthar at the inflated prices due to the unlawful conduct of Defendants. Local 322, like all similarly-situated Class members, has been damaged and has sustained economic injuries in the form of overcharges by the misconduct of Defendants, because it paid higher prices than it would have paid absent Defendants' improper actions described herein.

Adequacy of Representation

424. Local 322 can and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no interest that conflicts with or is antagonistic to the interests of the Class.

425. Local 322 is represented by counsel who are experienced and competent in the prosecution of complex actions, including consumer fraud class actions.

426. Plaintiff and its counsel are committed to the vigorous prosecution of this action on behalf of the Class and have the financial resources to do so.

Commonality

427. The factual and legal bases for Defendants' misconduct are common to Class members and represent a common thread of consumer fraud resulting in injury to Plaintiff and the Class. Common questions of law and fact in this case include, but are not limited to, the following:

a. whether Defendants engaged in the unlawful marketing and sales scheme alleged;

b. whether Defendants engaged physicians as "spoke-doctors" in the scheme involving KOLs alleged;

c. whether Defendants artificially inflated the prices of Acthar;

d. whether Plaintiff and the Class have been overcharged and thus damaged by paying artificially inflated prices for Acthar as a result of Defendants' unlawful conduct;

e. whether Defendants marketed and sold Acthar to beneficiaries of Plaintiff and the Class promoting a mode of action that remains unknown, and uses and doses that remain unapproved by the FDA;

f. whether Defendants engaged in the alleged conduct involving PAPs and the payment of patients copays in order to charge Plaintiff and the Class of TPPs the balance of the Acthar charge;

g. whether Defendants engaged in conduct in violation of New Jersey RICO;

h. whether Defendants engaged in conduct in violation of New Jersey antitrust laws;

i. whether Defendants engaged in conduct in violation of the New Jersey consumer Fraud Act;

j. whether Defendants have been unjustly enriched by their unlawful conduct;

k. whether Defendants negligently misrepresented Acthar to Plaintiff and the Class;

l. whether Defendants engaged in a conspiracy and/or aided and abetted others in deceiving Plaintiff and the Class about Acthar and Acthar pricing, and concealing the truth about its unlawful conduct;

m. whether Plaintiff and members of the Class are entitled to declaratory and injunctive relief as to Defendants' conduct;

n. whether Plaintiff and members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;

o. whether Defendants are liable to Plaintiff and the Class for statutory damages for conduct actionable under the antitrust, RICO and consumer fraud laws of New Jersey, including treble damages;;

p. the proper measure of damages; and

q. whether Plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

Predominance

428. These common questions of law and fact predominate over questions, if any, that may affect only individual members because Defendants have acted and refused to act on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' unfair and deceptive conduct alleged herein.

Superiority

429. A class action is superior to any other available method for the fair and efficient adjudication of this controversy in that, among other things, such treatment will permit a large number of similarly-situated persons and entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender.

430. The prosecution of separate actions by individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for Defendants which would, as a practical matter, be disparities of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

431. Defendants have acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

432. Accordingly, class certification is appropriate under Rule 23(b)(1)(A), 23(b)(1)(B), 23(b)(2) and 23(b)(3).

FORMATION OF THE UNLAWFUL ACTHAR MARKETING ENTERPRISE

433. Beginning in 2007 and continuing to the present, each Defendant implemented a marketing and promotion campaign by combining its own respective significant personnel and financial resources with peer-influencing physicians (known as KOLs) through which Mallinckrodt (i) falsely and deceptively oversold the mode of action, safety, efficacy, uses and doses of Acthar, (ii) failed to adequately warn of, and affirmatively misled the medical community regarding the mode of action, risks, benefits and value of Acthar, and (iii) unlawfully promoted Acthar for usage in populations for which it had not received FDA approval and for which the safety and efficacy had not been established through adequate clinical evidence. This association-in-fact created by Mallinckrodt is denominated in this Complaint as the "Acthar Marketing Enterprise. Mallinckrodt's associated participants – Cigna/Express Scripts [and their subsidiaries] and Ms. Pratta -- established the Acthar Marketing Enterprise to accomplish the common goal of causing increased prescribing activity of Acthar for off-label uses and doses for which Acthar was not proven to be safe, effective or useful. The scheme was accomplished through fraudulent, or false and deceptive, claims of efficacy and safety, medical usefulness, and for unlawful, off-label purposes.

434. First, to execute its Acthar Marketing Enterprise successfully, Mallinckrodt had to create a parallel marketing structure that appeared independent from the ordinary promotion forces – it did so both to avoid federal regulations concerning off-label promotion and to create the façade of independence behind the misleading message of safety, efficacy and non-indicated usage they each wished to promote. Mallinckrodt targeted primarily speaking events, seminars,

continuing medical education ("CME") events as well as other physician gatherings. Mallinckrodt, along with Cigna/Express Scripts and sales representatives like Pratta, worked with and paid leading KOLs to create content for such speaking events that misrepresented the safety, efficacy, and usefulness of Acthar for off-label uses, and paid these KOLs to deliver the disguised promotional messages to unsuspecting physician attendees.

435. The goal of the Acthar Marketing Enterprise was intentionally complementary and mutually reinforcing. Defendants' Acthar Marketing Enterprise succeeded in distorting and polluting the medical discourse and medical literature surrounding Acthar to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriateness of Acthar for off-label and label-expanding usage.

FORMATION OF THE ILLEGAL ACTHAR MARKETING ENTERPRISE

436. Defendants' Acthar Marketing Enterprise centered on hosting numerous events where KOL doctors solicited and/or approved by Defendants would falsely oversell the mode of action, efficacy and safety of Acthar, and would provide favorable information on the off-label use of Acthar, often under conditions where physicians would be compensated for attending the presentation. Defendants funded, and continue to fund, scores of such events between approximately 2007 to present.

437. The Acthar Marketing Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the mode of action of Acthar for the treatment of all diseases; (b) deliberately misrepresenting the safety and medical efficacy of Acthar for a variety of off-label uses; including 5-day dosing for MS exacerbations; (c) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Acthar for both approved indications

and for a variety of off-label uses and doses; (d) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Acthar; (e) wrongfully and illegally compensating physicians for causing the prescribing of Acthar; (f) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Acthar for both on-label and off-label uses, and then disseminating copies of such studies by the thousands to the medical community as part of their marketing; (g) intentionally misrepresenting and concealing Mallinckrodt's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Acthar to off-label markets; and (h) intentionally misrepresenting and concealing the financial ties between Mallinckrodt and other participants in the Acthar Marketing Enterprise.

438. Defendants' scheme reaped significant financial gain for all its participants. From 2007 to present, Mallinckrodt's revenues from the sale of Acthar soared into the millions and billions of dollars. These revenues were shared with Cigna/Express Scripts through Mallinckrodt's various contractual agreements with Cigna/Express Scripts, Accredo, CuraScript and UBC/Healthbridge. Eventually, as a result of Defendants' Acthar Marketing Enterprise efforts, and unbeknownst to the Plaintiff and Class Member TPPs, the vast majority of Acthar prescriptions were for off-label uses. Sales of each drug have grown at a significant rate each year. Currently, Acthar represents over $1 billion in revenue to Mallinckrodt, and its co-conspirators.

439. All of the participants in the Acthar Marketing Enterprise associated with each other with the common purpose of aiding them in marketing Acthar for off-label uses and to achieve "market expansion" of these uses. Each of the participants received substantial revenue or other consideration from Mallinckrodt for their efforts in the scheme to promote Acthar for

unapproved uses and doses. The more successful these marketing events were, the more events were would be in the future and the more fees and revenues each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist Mallinckrodt in their unlawful promotion of Acthar, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of hundreds of physicians throughout New Jersey and the United States, and that the promotion of Acthar for off-label indications by Defendants was illegal.

440. Defendants each exercised control over and participated in the Acthar Marketing Enterprise. Mallinckrodt compensated the other participants for their efforts, and controlled the money flow to the participating physicians. Mallinckrodt closely monitored all activities and events to ensure the expected representations and marketing messages related to the off-label uses of Acthar were made to physicians attending the events. Following such events, each Mallinckrodt tracked attending physicians' prescribing habits to ensure that the messaging was successful in causing prescribing activity for Acthar.

441. Cigna/Express Scripts did the same, directly and by and through its subsidiary entities, monitoring the activity of UBC employees who directly communicated with TPPs and patients about Acthar, and who prepared and disseminated periodic reports of such activities to Cigna/Express and Mallinckrodt. Pratta also prepared periodic reports of her activities in advancement of the objectives of the Acthar Marketing Enterprise to her superiors in Mallinckrodt.

Role of Physicians in the Acthar Marketing Enterprise.

442. One of the principal strategies pursued by Defendants in their Acthar Marketing

Enterprise was to target key physicians to serve as "thought leaders", or KOLs. These doctors promoted Acthar to their peers through peer selling programs by (i) touting Acthar's supposed off-label uses; (ii) claiming that Acthar was being widely u sed by other physicians for off-label uses; and (iii) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

443. To lure physicians to participate in the Acthar Marketing Enterprise, Mallinckrodt sales representatives and MSLs approached target doctors and informed them of an interest in funding research opportunities and clinical trials at their practices and institutions. Doctors who were willing to speak favorable about Acthar could receive substantial funds in the form of research grants or other monies. In addition, these doctors were frequently remunerated for other less-defined services, including "consulting" and "advisory board" services. Mallinckrodt instructed its sales department, and sales representatives like Defendant Pratta, to select doctors at the major teaching hospitals to become Acthar "experts' and KOLs who would in turn deliver the Acthar message to other physicians to row sales. This was done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice, or at a dinner or lunch roundtable.

444. Having recruited these physicians, the Acthar Marketing Enterprise created an explosion in the off-label use of Acthar by artificially creating the perception that physician specialists were clinically using Acthar and investigating with positive results their efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities and inducements. Defendants developed a stable of physicians to create this perception. Defendants paid these physicians to induce them to write PA denial appeals, letters to the editor and other documents that favorably discussed the off-label use of Acthar. Defendants also paid these

physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants'' meetings, speakers bureaus and similar events where the primary focus of the discussion was the off-label use of Acthar. The physicians who accepted these benefits and agreed to promote Acthar off-label to other doctors were physician participants in the Acthar Marketing Enterprise. The individual physician participants received tens of thousands of dollars, and in some cases hundreds of thousands, to promote the off-label uses of Acthar. Participation in the Enterprise through sham "authorships" and serving as presenting "faculty" at CME events and other honoraria also enhanced the physician participants' professional reputations.

445. The return on investment ("ROI") in the Acthar Marketing Enterprise was highly favorable.

446. Physician participants were absolutely critical to the success of the Acthar Marketing Enterprise. Indeed, the marketing plans drafted by Mallinckrodt required their participation. The participation of physicians allowed Mallinckrodt and its co-conspirators to disguise promotional events as educational events or consultants'' meetings. Moreover, as noted above, Mallinckrodt and Cigna/Express Scripts' UBC knew that peer-to-peer selling was far more persuasive than traditional drug rep detailing.[13] Primary care physicians are more likely to follow the advice of a Professor of Medicine at Johns Hopkins or another teaching hospital than that of a sales rep. By funneling the payments to physician participants through the vendor

[13] When a sales representative "details" a physician, often during a call to the physicians' office during work hours, the representative delivers to the physician the pharmaceutical company's key selling messages for one or more pharmaceutical products. In some cases, the sales pitch is accompanied by handing out free samples of the product and/or approved materials delivered to the physician, such as sales aids, slides or branded merchandise such as pens and prescription pads. Thus, sale representatives like Pratta were able to steer physicians through ASAP to UBC for PAP to ensure payment by TPPs like Plaintiff and the Class.

participants, the Acthar Marketing Enterprise could hide the speakers' financial ties with Mallinckrodt, and the Enterprise was able to mislead the physician-listeners into believing that the speakers were not biased and that the events were not promotional. As a result, the vast amounts of money the participating physicians received from the Defendants, for speaking and other purposes, was largely hidden from the physicians who attended events at which the participating physicians spoke.

447. Physicians who participated in the Acthar Marketing Enterprise either as speakers or as authors, entered into mutually advantageous contractual relationships with Mallinckrodt. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees, consulting fees, advisory board fees, and research grants. Physicians who refused to deliver the favorable off-label message that Defendants wanted were blackballed and would not receive additional payments.

448. The participating physicians knew that minimal scientific evidence supported the use of Acthar for the off-label uses and that the type of clinical evidence that existed was insufficient, under the accepted standards in the medical profession, to represent that Acthar worked for the unapproved indications.

449. All of the physician participants had personal relationships with employees of Mallinckrodt an Cigna/Express Scripts, whether the Mallinckrodt sales reps or MSLs, the UBC RSs, the Cigna/Express Scripts account representative, or the Accredo pharmacist, and frequently Defendants recommended specific individual participants for event.

450. Plaintiff does not at this time know the identity of all of the physician participants, which likely number in the hundreds. Only the Defendants know such information, which is in their exclusive control.

451. The Acthar Marketing Enterprise sponsored hundreds of events across the country between 2007 and the present. Through Propublica, the Plaintiff is only able to identify physicians by payments, including travel, food, lodging and entertainment benefits they received for events held at resorts or out of town hotels.

452. In order to implement their respective plans to transform Acthar into the blockbuster drug it has become, despite a small on-label patient population, Acthar created a separate Acthar Marketing Enterprise composed of Mallinckrodt, Cigna/Express Scripts, CuraScript, Accredo, UBC and dozens of physician participants, some of whom are listed above and others whose identities will be revealed in discovery. These participants all acted together and under Mallinckrodt's and Cigna/Express Scripts' control in promoting Acthar's off-label to the healthcare industry, employing numerous tactics with an enormous degree of success.

453. Defendants hosted numerous meeting, seminars and events over the course of several years that were falsely represented to be neutral, educational forums. At these events, the roster of physician participants provided misleading and deceptive information to fellow physicians on the off-label uses of Acthar (i.e. peer-to-peer marketing). The physician participants were not independent, but received behind-the-scenes coaching and remuneration from Defendants and/or their vendors, and often used slide decks and PowerPoint presentations prepared by the marketing teams of Mallinckrodt and Cigna/Express Scripts that targeted audience members, many of whom were primary care physicians or specialists in MS, NS and RA, were not aware that the specialists (including prominent neurologist and nephrologists) speaking to them were in fact delivering, and being paid to deliver, the off-label marketing messages of Defendants.

454. In addition, the sales force of Mallinckrodt promoted Acthar to physicians

through "details" or sales calls to physicians' offices. Defendant Pratta was one such sales representative and has admitted her direct knowledge of and role in such conduct by her qui tam complaint.

455. On these sales calls, sales representatives, often using a sales aid and/or sales script developed by Mallinckrodt, "detail" the physician on the mode of action and off-label uses and doses of Acthar. In addition, the sales representatives like Pratta were instructed to deliver to physicians reprints of medical journal articles advocating the off-label use of Acthar, many of which were created by the KOLs paid by Mallinckrodt, and to notify physicians of and ask for their attendance at upcoming CME events and lectures sponsored by Mallinckrodt pursuant to the Acthar Marketing Enterprise. All aspects of the Acthar Marketing Enterprise were mutually reinforcing.

456. All components of the Acthar Marketing Enterprise were fully integrated and operated under Mallinckrodt's exclusive control, through the ASAP program.

DEFENDANTS' USE OF THE MAILS AND WIRES TO CREATE AND MANAGE THEIR FRAUDULENT SCHEME

457. Defendants used, and knowingly caused the use of, mail and interstate wire communications to create, execute, and manage its fraudulent schemes, as well as to further them. This scheme involved the national marketing and sale plan that comprised ASAP, and encompassed physicians and consumers across the country.

458. Defendants' use of, and causing the use of, the mails and wires in furtherance of their schemes to defraud involved thousands of communications and transmission through the Class period all over the country, including:

- Transmission through mail and wire marketing and advertising materials about the off-label uses of Acthar to and from physicians across the country, including

and especially the Acthar Start Forms which all were faxed to UBC, and then sent by UBC to Accredo and other SPPs;

- Communications and transmissions, including financial payments, from Defendants or vendors to participants in the Acthar Marketing Enterprise, including physicians, discussing and relating to the production and publication of articles and dissemination of materials misrepresenting the off-label uses and safety and efficacy of Acthar.

- Communications with Plaintiff and the Class Members and their beneficiaries, other health insurers, and patients, including communications about the Acthar mode of action, uses, doses, approvals, prior authorizations, denials, appeals and payments for Acthar, all caused to made based on misrepresentations concerning their mode of action, safety, efficacy, effectiveness, and usefulness of Acthar as communicated by Defendants; and

- Communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Mallinckrodt's improper scheme.

459. In addition, both Mallinckrodt's corporate headquarters and the business offices of UBC (in four locations), Accredo (in multiple locations across the country) and CuraScript (in several different locations) have communicated, and knowingly caused communications, by United States mail, telephone and facsimile with or by various local district managers, MSLs, RSs, pharmaceutical sales representatives, and others, in furtherance of Defendants' scheme.

Cigna/Express Scripts and the Case of Daraprim

460. Turing Pharmaceuticals, LLC ("Turing") acquired the rights to Daraprim and proceeded to increase the price 5000% from $13.50 to $750.00 per pill. One year's course of treatment rose from $6,500 to $361,000.

461. Strikingly, Cigna's Express Scripts employed its market power to counter Turing's action. It worked to create an alternative that was much less expensive than Daraprim.

462. On December 1, 2015, ESI announced that it would "partner with Imprimis Pharmaceuticals to drive access to a low-cost alternative to Daraprim." See, "ESI Champions $1 per Pill Access to an Alternative for Daraprim", December 1, 2015, at: http://lab.express-

scripts.com/lab/insights/drug-options/express-scripts-champions-1-per-pill-access-to-an-alternative-for-daraprim In partnership with ESI, "Imprimis [] offer[ed] a compounded oral formulation of pyrimethamine and leucovorin (a form of folic acid) for as low as $1 per capsule for people whose pharmacy benefit is managed by ESI." *Id.* When it is in ESI's interest, it acts to "improve access and affordability." *Id.*

463. ESI's Chief Medical Officer, Dr. Steve Miller, stated that ESI found a way to deliver "a safe, high-quality and extremely cost-effective way to provide access to a Daraprim alternative." However, because of its agreement with Mallinckrodt, ESI has not served as an effective agent for pharmaceutical buyers to seek to lower the cost of Acthar, or the availability of reasonably priced alternatives.

The Views of Express Scripts' Chief Medical Officer, Dr. Steve Miller, on Express Scripts' Market Power and the Value of Acthar for What is Being Charged.

464. Beginning in 2007, Express Scripts became the exclusive agent of Mallinckrodt for the distribution of Acthar. See Freudenheim, supra. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, Express Scripts did not push back. Instead, when confronted with the 2007 price increase, ESI's Chief Medical Officer Steve Miller stated that "[t]he increase was a manufacturing decision. I can't comment on it." *Id.*

465. The circumstances demonstrate why Dr. Miller chose to stay silent in the face of Express Scripts' decision to join Mallinckrodt in overcharging payors for Acthar.

466. By the time Local 322was paying for Acthar, Express Scripts was handling each and every aspect of Acthar distribution through the above-described functions. CuraScript was the exclusive specialty pharmaceutical distributor, Accredo was the specialty pharmacy provider, and UBC coordinated both the product and money flows through the ASAP Program. As Mallinckrodt's exclusive agent, Express Scripts had no interest in lowering the price for Acthar

because it was making money off all aspects of its exclusive arrangement with the manufacturer. In other words, by helping Mallinckrodt maintain and enhance its monopoly power in the ACTH market, Express Scripts along with Mallinckrodt realized greater profits at the expense of payors like Local 322.

467. In the spring of 2017, ESI's Senior Vice President of Supply Chain and Specialty Pharma, Everett Neville, stated, "I don't think [Acthar is] a very great [drug] – it's a pretty poor drug with a very limited need and certainly [ESI's Chief Medical Officer, Dr.] Steve[Miller] could comment."14 Mr. Neville went on to say, "I think [Dr. Miller] and I both would agree, and I think everybody in our company would agree, that [Acthar] is vastly overpriced for the value."15 (emphasis added). Mr. Neville stated that he "personally told [Mallinckrodt's] management team that their drug is hugely overpriced and that he "know[s] [Dr. Miller] has as well."16

468. In the same public setting, Dr. Miller stated, "[i]f you look at the data, the indications for the drug are...in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace and so we're going to continue to be very vigilant in our utilization management."[17]

469. Despite this express acknowledgment by ESI's Chief Medical Officer, in the

[14] https://cnafinance.com/mallinckrodt-mnk-stock-dives-on-citron-sell-side-report/15565 ; *see also*, Full May 19, 2017 Citi Research Telephone Conference Call Transcript, available at: https://ir.citi.com/l2GW3%2FspXqa99R2rvpFJS8QKZpf%2BRi62n5DFshd7bPciqQPr7uiAlekB%2FjbbEhWR

[15] *Id.*

[16] *Id.*

[17] *Id.*

weeks and months following Mallinckrodt's settlement with the FTC, Express Scripts had not acted or made any efforts to contain costs or provide a reasonable alternative for Acthar.

470. Dr. Miller has articulated the power of Express Scripts in the prescription drug marketplace to extract lower prices for its customers, using its tremendous buying power and influence. He has made all of the following public comments:

> "When I joined the company, we represented 12 million members. We're at 85 million today. That gives us extraordinary sway in the marketplace. If you think about any other aspect of health care, no one else has that many lives that they can represent." [18]

> "We have tremendous scale, which allows us to get the best deals for our plan sponsors from both the pharmaceutical manufacturers and also the pharmacies. If any pharmacy chain ever becomes too large, we're able to move our patients and … get the lowest cost." [19]

> "I think that because of the continued escalation of cost, you need a PBM now more than ever. And what a best-in-class PBM like Express Scripts does really ensure is great health outcomes and more affordable costs." [20]

> "Pharma has shown that they feel very emboldened with their pricing power. We're using our clout in the marketplace to really tamp these down for our clients." [21]

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[18] *Managed Care Magazine Online*, "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma," by Peter Wehrwein, April 2015, https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

[19] *Business Insurance*, "Q&A: Dr. Steve Miller, Express Scripts Holding Co.," by Shelby Livingston, May 22, 2016, http://www.businessinsurance.com/article/00010101/STORY/305229991/Q&A-Dr-Steve-Miller,-Express-Scripts-Holding-Co

[20] *Managed Care Magazine Online*, "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma," by Peter Wehrwein, April 2015, https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

[21] *Nightly Business Report*, "Express Scripts Looks to Limit Drug Price Increases," by Meg

"There are pharma companies that recognize this is in their best interest," he says. "They, like us, want to get to a sustainable marketplace. They know if they're overcharging for drugs that have very little efficacy, that puts them in a competitive disadvantage."[22]

"Discussions to control costs have never been more important, as recent estimates put global drug spend at $1.5 trillion by 2021, according to data from Quintiles IMS Holding. Yet sometimes, in the drug pricing debate, blame is placed on one part of the drug distribution system when, in fact, all of us – pharmaceutical companies, pharmacy benefit managers (PBMs), policymakers and payers – have a role to play in achieving better affordability and accessibility for medicine. As the largest PBM, our job is to make sure our patients, and our clients who provide them a pharmacy benefit, are getting medicines at the lowest net cost while working with our industry partners to make that possible."[23]

"…[I]t is incumbent upon the pharmacy benefits managers to more forcefully illustrate the critical role we play in making medicine more affordable and accessible. For example, we partnered with a drug maker who was willing to lower the price of its hepatitis C drug. In doing so, we were able to provide 50,000 patients affordable access to this medication."[24]

"The biggest problem is not new expensive drugs but repricing old ones, and not just ones being purchased by Martin Shkreli or Valeant. You have no new research. You have no innovation. You have nothing but increased drug prices."[25]

"We are constantly trying to be vigilant and chase the bad actors out of the

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Tirrell, October 2, 2015, http://nbr.com/2015/10/07/express-scripts-looks-to-limit-drug-price-increases/

[22] *Medical Marketing and Media*, "Express Scripts' Steve Miller Takes on Drug Industry in Pricing Battle," by Jaimy Lee, February 1, 2015, http://www.mmm-online.com/payersmanaged-markets/express-scripts-steve-miller-takes-on-drug-industry-in-pricing-battle/article/460559/

[23] *Real Clear Health*, "Is Drug Pricing at an Inflection Point?" by Dr. Steve Miller, April 14, 2017, http://www.realclearhealth.com/articles/2017/04/14/is_drug_pricing_at_an_inflection_point_110550.html

[24] *Id.*

[25] *Forbes, Pharma & Healthcare*, "Solving Pharma's Shkreli Problem," by Matthew Herper, January 20, 2016, https://www.forbes.com/sites/matthewherper/2016/01/20/solving-pharmas-shkreli-problem/#56774fd26be3

marketplace." [26]

471. Through such statements, Express Scripts acknowledged its strong influence on pharmaceutical markets. The striking feature of the current circumstance is that Express Scripts has not asserted its influence to effectuate lower prices for Acthar.

472. While acknowledging the "value" of the medication does not warrant its high prices, Express Scripts has facilitated, rather than forestalled, Mallinckrodt's desire for ever growing profits by "repricing" an "old drug".

473. With Acthar, "[y]ou have nothing but increased drug prices," due in large part to Express Scripts' decision to withhold its market power to effectuate cost containment through lower prices.

The Mallinckrodt Synacthen Acquisition

474. Since 2007, Acthar has represented 98% or more of Mallinckrodt's revenue. Acthar was so important to Mallinckrodt that its then-CEO Don Bailey told investors it "is basically a single product company."

475. Through its exorbitant price increases, Mallinckrodt was able to grow its revenue from Acthar sales from less than $1 million in 2001 to $798.9 million in 2013, to over $1 billion in 2018. Much of this increase occurred between 2011 and 2013 when Mallinckrodt's revenues increased $218.2 million to $798.9 million.

476. However, by 2013, Mallinckrodt identified a competitive threat. Novartis AG ("Novartis") developed Synacthen Depot (cosyntropin depot) ("Synacthen"), a synthetically derived ACTH medication, which, like Acthar, could be injected intra-muscularly. While it was

[26] *The New York Times*, "Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out," by Katie Thomas, January 9, 2017, https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html

used outside the United States, it was not yet approved by the FDA for use in the United States. Recognizing that the entry of Synacthen in the United States market for ACTH drugs would threaten its exercise of its monopoly power, Mallinckrodt first attempted to buy the rights to Synacthen in 2009. It failed.

477. As of 2013, Novartis agreed to sell Synacthen to Retrophin, Inc., which at the time was helmed by Mr. Martin Shkreli. Mr. Shkreli founded Turing (the maker of Daraprim) after he departed Retrophin.

478. When faced with a competitive threat to its monopoly, Mallinckrodt disrupted the bidding process for Synacthen by intervening at the last minute to pay multiple times what had been offered by three competitors, including Retrophin. Retrophin had agreed to buy Synacthen for $16 million. Upon learning of this imminent threat, Mallinckrodt acted to protect and enhance its monopoly power by licensing Synacthen for a minimum of $135 million from Novartis. It licensed the United States exclusive rights to Synacthen from Novartis, not to bring this viable synthetic alternative to Acthar to market, but to eliminate the nascent competitive threat posed by an independently owned Synacthen.

479. These actions allowed Mallinckrodt to maintain and enhance its monopoly power in the ACTH market. The Synacthen acquisition had the purpose and effect of suppressing competition and allowing Mallinckrodt to continue to raise prices for Acthar, which it did.

480. From 2013 through 2017, Mallinckrodt and Cigna/Express Scripts raised the price of Acthar from $36,144 to $43,658.

481. Unlike in the case of Daraprim, Cigna/Express Scripts did nothing to prevent the maintenance of Mallinckrodt's monopoly over Acthar in the ACTH market. Cigna/Express Scripts had the power – through its direct contractual arrangements with Mallinckrodt and

otherwise – to force Mallinckrodt to either bring Synacthen to market as a competitor to Acthar, or license the drug to another company to compete with Acthar. It did neither. Instead, the federal government had to force Mallinckrodt to license Synacthen to a competitor as part of the settlement of its case.

Relevant Markets and Monopoly Power,
and the FTC Complaint Against Mallinckrodt

482. The supracompetitive and exorbitant prices that Defendants charge for Acthar, and Mallinckrodt's limitations on distribution through the entry into an exclusive distribution arrangements with Cigna/Express Scripts in 2007, are direct evidence of Mallinckrodt's monopoly power and actions to maintain and enhance such monopoly power, in violation of the New Jersey antitrust laws, in conjunction with Cigna/Express Scripts. That Acthar holds a dominant share of the relevant market for ACTH drugs in New Jersey, as well as the United States, shows Mallinckrodt's monopoly power by indirect evidence.

483. The relevant product market is the sale of ACTH drugs, dominated by just one product, Acthar. The geographic market is the State of New Jersey. In this market, Mallinckrodt is the single seller, and the third-party payors are the leading buyers.

484. The ACTH market is and has been characterized by significant barriers to entry.

485. There are no medical or reasonably available substitutes for Acthar. The only potential substitute was Synacthen, for which Mallinckrodt purchased the rights from Novartis in 2013, only to shelve the product rather than seek to bring it to market in New Jersey and the United States. But, Mallinckrodt and Cigna/Express Scripts agreed that Mallinckrodt would not bring Synacthen to market after it was acquired.

486. On January 18, 2017, the Federal Trade Commission ("FTC") sued Mallinckrodt, alleging that Mallinckrodt exercised, and continues to exercise, monopoly power in the United

States in the sale of Acthar. See generally, Complaint for Injunctive Relief and Other Equitable Relief ("FTC Complaint") 1:17-cv-00120 (District of Columbia) at ECF No. 1.

487. The FTC alleged that such purchases "extinguished a nascent competitive threat to [Mallinckrodt's] monopoly." FTC Complaint, ¶ 1.

488. At all relevant times material to this case, Mallinckrodt possessed monopoly power – the ability to profitably raise price significantly above competitive levels without losing significant sales – in the relevant product market. None of the vast price increases taken by Mallinckrodt between 2007 and the present have caused a significant loss of sales. To the contrary, Mallinckrodt's sales have increased during that time.

489. Mallinckrodt has repeatedly and profitably raised Acthar's price from the time it acquired the product for $100,000 in 2001 from Aventis to the present. Mallinckrodt has been able to raise prices unchecked, as set forth above, and achieve corresponding revenue growth to more than $1 billion.

490. Mallinckrodt has encountered no competitive constraints on its ability to repeatedly increase Acthar's price and, by extension, its revenue and profit margins. Mallinckrodt does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications, except for IS.

491. Indeed, one Mallinckrodt executive commented that the price for Acthar "was chosen by looking at the prices of other specialty drugs and estimating how much insurers and employers would be willing to bear."[27] Mallinckrodt took "some comfort that the strategy would

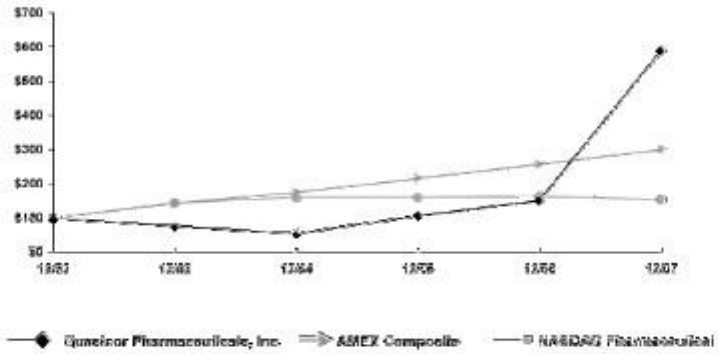
[27] https://www.nytimes.com/2008/04/19/business/19specialty.html

work, and physicians would continue to use the drug, and payers would pay."[28] In fact, according to Mallinckrodt, "the reality was better than we expected."[29]

492. In its Annual Report on Form 10-K for the Fiscal Year ended December 31, 2007, Questcor illustrated the effect of its monopolization strategy on its "5 Year Cumulative Total Return", illustrating a 290% return between 2006 and 2007 as follows:

Comparison of 5 Year Cumulative Total Return*
Among Questcor Pharmaceuticals, Inc.,
the Amex Composite Index
and the Nasdaq Pharmaceutical Index

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Questcor Pharmaceuticals, Inc., The AMEX Composite Index
And The NASDAQ Pharmaceutical Index



	Cumulative Total Return*					
	12/02	12/03	12/04	12/05	12/06	12/07
QUESTCOR PHARMACEUTICALS, INC.	100.00	75.51	54.08	106.13	151.02	588.78
AMEX COMPOSITE INDEX	100.00	143.18	175.20	215.26	257.04	299.37
NASDAQ PHARMACEUTICAL INDEX	100.00	144.89	160.46	160.65	163.42	154.46

* $100 invested on 12/31/02 in stock or index-including reinvestment of dividends. Fiscal year ended December 31.

This stock performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

493. As discussed at length above, FDA approval is required to market pharmaceuticals to United States consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for United States consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

[28] *Id.*

[29] *Id.*

494. Acthar has a 100% share of the market for ACTH drugs in New Jersey and the United States. No other ACTH drug is FDA-approved for therapeutic use.

495. The New Jersey ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's current CEO, Mark Trudeau, assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way from a generic perspective."[30]

496. Former President and CEO Don Bailey also claimed that one of the barriers to entry in the marketplace is the Acthar drug formulation. While Acthar is a biologic extraction of porcine pituitaries, Bailey claimed, "[i]t's an undisclosed composition, so that's a trade secret." He also claimed "[t]he manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process. We have exclusive worldwide rights to Acthar, so we own it lock, stock and barrel…The composition of Acthar that comes out of the manufacturing process is tied to the process, so if you don't know the process you can't figure out what's actually in Acthar."[31]

497. If what the former CEO was saying was that Mallinckrodt enjoyed a natural monopoly, that does not necessarily imply the absence of market constraints. These constraints can come from a new competitive product or from a dominant buyer on the other side of the

[30] https://www.sec.gov/Archives/edgar/data/891288/000119312514133757/d707613d425.htm

[31] https://www.sec.gov/Archives/edgar/data/891288/000119312511225705/dex991.htm

market. Both of these factors are relevant here.

Mallinckrodt Engaged in Anticompetitive Conduct By Acquiring the Only Competitor Drug, Synacthen, and Refusing to Bring it to Market to Compete with Acthar, with Cigna/Express Scripts Complicity.

498. Synacthen posed a threat to Mallinckrodt's ACTH drug monopoly, so Mallinckrodt intervened at the time when other firms were attempting to acquire the United States rights to Synacthen from Novartis. Mallinckrodt submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Mallinckrodt eliminated the possibility that another firm would develop it and compete against Acthar.

499. Synacthen constituted a nascent competitive threat to Mallinckrodt's ACTH drug monopoly, notwithstanding the uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

500. For years, Mallinckrodt viewed Synacthen as a significant potential competitive threat to its monopoly.

501. When Mallinckrodt first decided to pursue an "orphan drug" (i.e., high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar's revenue growth.

502. Nevertheless, in 2007, it adopted and pursued the above-described "new strategy", along with Cigna/Express Scripts, by consolidating Acthar distribution to just one distributor and streamlining its control over sales and distribution through the implementation of ASAP. These functions were consolidated in one significant company, Express Scripts, the largest PBM at the time.

503. In 2009, Mallinckrodt brought Gregg LaPointe back to its Board of Directors. At the time, he was serving as Sigma-Tau's CEO in Gaithersburg, Maryland. As the then Board

Chairman, Virgil Thompson announced:

> "We are delighted to welcome Gregg back to Questcor. He brings to our Board and shareholders significant pharmaceutical and public company experience, as well as hand on operational familiarity with therapies that treat patients with rare diseases. As we continuously ***explore additional opportunities*** for our product, H.P. Acthar(R) Gel to meet the unmet medical needs of patients, ***Gregg will bring valuable perspective to our Board.*** We look forward to working with him again."

504. One such "additional opportunity" was Mallinckrodt's acquisition of Synacthen. In 2009, Mallinckrodt approached Novartis about acquiring Synacthen. At that time, Mallinckrodt continued to view Synacthen as a possible future competitor, especially given the increasing prices Mallinckrodt was commanding for Acthar. Unsuccessful in that initial attempt, Mallinckrodt continued to monitor the competitive threat from Synacthen.

505. Then in 2012, Mallinckrodt again concluded that Synacthen posed a more immediate threat to Acthar if Synacthen was approved for sale in the United States.

506. By 2013, Mallinckrodt feared that if another company were to acquire Synacthen and obtain FDA approval, it could undermine its business model.

507. On information and belief, as long as Mallinckrodt believed no other firm was seeking to bring Synacthen to the United States, Mallinckrodt did not make further attempts to acquire it. Indeed, just months before Mallinckrodt began pursuing the acquisition of Synacthen, top Mallinckrodt officials questioned whether Synacthen would provide any affirmative value to Mallinckrodt.

Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly

508. Unbeknownst to Mallinckrodt at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug was already approved and sold. Dozens of companies contacted Novartis and expressed interest

in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements. One of these three was Retrophin. Another was Cerium Pharmaceuticals, Inc. ("Cerium"), with a corporate headquarters in Gaithersburg Maryland where Gregg LaPointe, the new company's CEO, lived.

509. Cerium's website describes it as follows:

> Cerium Pharmaceuticals, Inc. is an emerging biopharmaceutical company dedicated to the development and commercialization of medicines for patients with rare (orphan) diseases. Cerium's core focus is to acquire currently marketed products and mid-to-late stage development compounds for rare diseases, leveraging basic discovery work already performed by others that has established project feasibility. Cerium's unique business model pairs a core management team of rare disease experts; with an extensive network of academic researchers, specialized consultants, third party service providers and contractors. We have expertise in clinical development, regulatory affairs, and commercialization of rare disease medicines. Based on our extensive and successful experience, we employ an optimized infrastructure to quickly develop and commercialize new orphan medicines.

510. It is unclear what, if any, "medicines for patients with rare diseases" Cerium actually owned as of 2011. Nevertheless, it [through LaPointe] made bid for Synacthen.

511. It is believed and therefore averred that Cerium was a straw buyer, whose only interest in Synacthen was to prevent others, like Retrophin, from obtaining the rights to Synacthen. It is believed that LaPointe was continuing to coordinate his efforts ostensibly on behalf of Cerium with Mallinckrodt, to assist it in maintaining its monopoly power over Acthar and the ACTH market.

512. This belief is bolstered by several facts.

513. First, in a highly unusual move, Cerium approached the FDA and successfully obtained orphan drug status for Synacthen prior to actually acquiring the rights to the drug. Cerium announced the success of this move on its website in November 2012.

514. Second, as part of Project "Zodiac", the name Mallinckrodt applied to its plan to acquire Synacthen, Mallinckrodt was fully aware as of at least January 2013 of the amount of Cerium's bid -- $40 million – and other confidential terms of its offer to Novartis, despite the confidential nature of the sealed bid process Novartis was conducting. Only LaPointe, a twice former Board member of Mallinckrodt would have any interest in revealing to Mallinckrodt the terms of Cerium's supposedly confidential bid.

515. Third, in December 2012, Mallinckrodt CEO Don Bailey and COO Steve Cartt exchanged emails in which Bailey acknowledged that there was a delay in the negotiating process "because they [Novartis] are further negotiating with others due to [Mallinckrodt's] entry [into the bidding process] (raised the price for others)." Brackets added, parenthesis in original. Carrt responded that "[w]e want to move this along while appearing firmly interested but not overly so. This has definitely thrown a curve ball into the process for Greg el al that will be tough for them to deal with given that they are VC [venture capitalist]-backed. Those guys do not like to put their cash up front. This is a very interesting process." It is believed that the "Greg" referenced is LaPointe.

516. Mallinckrodt didn't want to overpay for acquiring the rights to Synacthen, because they only wanted the produce to prevent others from competing with Acthar's monopoly.

517. However, it is alleged that each of the three bidding firms planned to develop Synacthen for IS and to use Synacthen to compete directly with Acthar. With this indication, each firm expected to capture a significant share of the United States ACTH market from Questcor by pricing Synacthen below Acthar's prices. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business

plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the United States ACTH market.

The Value of the Synacthen Assets

518. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation had been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

519. The asset package being sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

520. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation de novo, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

Mallinckrodt Disrupted the Synacthen Bidding Process

521. It is alleged that in October of 2012, Mallinckrodt learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis to develop it to compete with Mallinckrodt for the United States ACTH market. Mallinckrodt immediately reached out to Novartis, signed a confidentiality agreement with Novartis, and submitted a confidential offer for the purchase of Synacthen.

522. Novartis negotiated with the three alternative bidders in parallel with Mallinckrodt. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition

with Acthar. At the point where those negotiations left off, each company exchanged deal terms with Novartis and submitted formal offers. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on United States sales of Synacthen.

523. Unlike the three alternative bidders, Mallinckrodt had only incomplete plans, at best, for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis. Retrophin ultimately prevailed in the bidding war with a bid of $16 million.

524. However, on June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Mallinckrodt and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"). By the Agreements, Mallinckrodt gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Mallinckrodt was obligated to pay a minimum of $135 million, and likely $300 million, to Novartis for Synacthen.

525. In other words, Mallinckrodt swept in at the eleventh hour to overpay—at least 8 times more than the market had determined—for the only immediate competitive threat to its monopoly for Acthar. Despite paying this amount, they did not seek FDA approval to bring the product to market.

The Lawsuit Between Retrophin and Mallinckrodt for Its Antitrust Violations

526. In January 2014, Retrophin sued Mallinckrodt for antitrust violations in the United States Federal District Court for the Central District of California. See, Retrophin, Inc., v. Questcor Pharmaceuticals, Inc., CV-14-00026-JLS (C.D.Cal.) ("Retrophin Complaint"). To the extent relevant to Plaintiff's Complaint, the averments regarding antitrust conduct interposed by Retrophin are incorporated by reference herein.

527. In the Retrophin Complaint, Retrophin claimed:

> In June of 2013, plaintiff Retrophin was poised to challenge Questcor's monopoly. It had negotiated an agreement to purchase from Novartis AG ("Novartis"), the rights to sell in the US a product called Synacthen. ...
>
> Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questcor by dramatically undercutting Questcor's price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.
>
> On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In doing so, it preserved and entrenched its ACTH monopoly in the US and eliminated the competitive threat posed by Retrophin's acquisition of Synacthen. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

Retrophin Complaint, ¶¶ 4-6.

528. The FTC agreed with Retrophin's assessment.

529. The government, in its 2017 FTC complaint, mirrored Retrophin's 2014 allegations that Mallinckrodt engaged in anticompetitive conduct in violation of antitrust laws.

530. Mallinckrodt chose to settle the lawsuit with Retrophin for $15.5 million, slightly less than the $16 million Retrophin bid to purchase Synacthen from Novartis.

Mallinckrodt's Acquisition of Synacthen Harmed Competition in New Jersey

531. Mallinckrodt's strategy to protect its monopoly power in the market for ACTH drugs was successful. But-for Mallinckrodt's acquisition of Synacthen, one of the three alternative bidders, including Retrophin, would have acquired Synacthen and pursued its plan to develop Synacthen for IS to compete directly with Acthar at a lower price. With the acquisition of Synacthen, Mallinckrodt was able to thwart an imminent threat to its Acthar monopoly and thereby harmed competition.

532. Mallinckrodt claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the similarities between the two drugs, any therapeutic indication that Mallinckrodt was to pursue for Synacthen could easily have been pursued for Acthar.

533. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar and Synacthen.

534. However, despite its claims, Mallinckrodt has not brought Synacthen to market for any indication. Instead, it keeps Synacthen off the market to protect its monopoly power and high prices for Acthar.

535. Cigna/Express Scripts has done nothing to force Mallinckrodt to bring Synacthen to market, or license it to a competitor, despite its direct contractual agreements with Mallinckrodt and power to force such conduct as the largest buyer's agent in the market.

Mallinckrodt settles with the FTC

536. On January 18, 2017, the FTC announced that Questcor and its parent Mallinckrodt agreed to pay $100 million to settle FTC charges that Questcor and Mallinckrodt violated antitrust laws when Questcor acquired the rights to Synacthen from Novartis in 2013.

537. According to FTC Chairwoman Edith Ramirez, "Questcor took advantage of its monopoly to repeatedly raise the prices of Acthar, from $40 in 2001 (when it acquired the rights to sell Acthar for $100,000) to more than $34,000 per vial today – an 85,000 percent increase."

538. The brunt of these monopoly prices was borne by self-funded payors, like Local 322, located throughout the country, whose beneficiaries and patient members had children with IS or were afflicted with MS and were at the mercy of Mallinckrodt.

539. From the time it sought FDA approval for the treatment of IS, Mallinckrodt has raised the price of Acthar to over $43,000.

540. Mallinckrodt claimed that these exorbitant price increases were in response to demand. But its former Chief Executive Officer, Don Bailey, acknowledged in 2009 that "we only have about 800 patients a year. It's a very, very small – tiny – market."32 Consequently, the limited use of the product did not justify an over 58,000% price increase from acquisition until 2009.

541. Since the Acthar market for the treatment of IS was so limited, Mallinckrodt sought to expand its use. By 2012, Acthar was prescribed for Medicare recipients 3,387 times. To Medicare alone, this represented a cost of $141,500,000 in 2012.

542. Quantified another way, Dr. William Shaffer, a neurologist in Greeley, Colorado who was the highest prescriber of Acthar in 2012, wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare $4,000,000.

543. Acthar represented 98% or more of Mallinckrodt's sales and revenue from sales since 2007. Its manipulation of the market has resulted in a 266% increase in revenue year-over-year from 2011 to 2013. Total net sales for Mallinckrodt in 2011 were $218.2 million, $509.3 million in 2012, and $798.9 million in 2013. In each of those years, Acthar represented at least 95% of Mallinckrodt's net sales – over $1.45 billion in revenue.

544. In the words of then-CEO Don Bailey, "Questcor is basically a single-product company." But, by flexing its monopoly power, Questcor has been able to raise Acthar prices and increase revenue from Acthar in a "tiny market" from less than $1 million for fiscal year 2001 to $799 million for fiscal year 2013 – a nearly 80,000% increase. It did so in conjunction with Express Scripts.

545. Mallinckrodt's decision to exclusively contract with the agent for its largest

[32] https://www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html

customer to provide limited distribution for Acthar removed ESI's competitive pressure in the marketplace to cause Acthar prices to be lower. Instead, by entering into an exclusive arrangement with Express Scripts, Mallinckrodt was able to enhance its monopoly power and to raise its Acthar prices above competitive prices throughout the relevant time period from 2007 through the present.

MALLINCKRODT MISREPRESENTS AND DECEIVES ABOUT THE QUALITY, CHARACTERISTICS, CONDITION, BENEFITS AND OTHER ASPECTS OF ACTHAR, TO TRY TO JUSTIFY ITS HIGH PRICE

546. Mallinckrodt has consistently misrepresented and concealed the truth about Acthar, including why it price has been raised to the current exorbitant levels. These misrepresentations and deception have caused Local 322 and other payors to pay the exorbitant prices for Acthar charged by Express Scripts and Mallinckrodt, despite Express Scripts' admission in 2017 that Acthar was not worth the price Express Scripts was charging for it.

Willful Misrepresentations and Deception in the Face of a Congressional Inquiry into and Payer Scrutiny of Acthar's Pricing Without Evidence of Superior Medical Efficacy.

547. When the United States Committee on Aging began to investigate why certain pharmaceutical companies appeared to be taking advantage of the national healthcare system to enrich themselves and their executives, Mallinckrodt actively sought to deflect Congressional attention away from Acthar by misrepresenting and concealing the truth.

548. In late 2016, just before Mallinckrodt's settlement with the FTC was announced, Susan Collins, Senator from Maine, and Claire McCaskill, Senator from Missouri (where Mallinckrodt is headquartered), issued a 130-page report titled "Sudden Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the

United States Health Care System."[33]

549. Chairman Collins announced that the report was "the culmination of the Senate Aging Committee's year-long, bipartisan investigation into the egregious price increases on a number of decades-old drugs acquired by pharmaceutical companies that act more like hedge funds. We must work to stop the bad actors who are driving up the prices of drugs that they did nothing to develop at the expense of patients because, as one executive [Martin Shkreli of Turing Pharmaceuticals, then Retrophin, Inc.] essentially said, 'because I can.'"[34]

550. Ranking Member McCaskill added, "[t]he hedge fund model of drug pricing is predatory, and immoral for the patients and taxpayers who ultimately foot the bill."[35]

551. In the face of such scrutiny, Mallinckrodt was asked "if it was worried that Congress might soon examine its operations. After all, Acthar's pricing patterns is very similar to those of the companies singled out by the Senate Aging Committee."[36]

552. Mallinckrodt's company spokesman responded that "Mallinckrodt believes it has none of the characteristics that troubled the Aging Committee about the four companies it studied." For example, he noted "Acthar is not a drug with no immediate competition, and Mallinckrodt has not controlled access to it through a closed distribution systems. Neither does the drug serve a small market, which would make unattractive to competitors." He also stated, "Mallinckrodt did not dictate Acthar's price when it acquired it [as part of the acquisition of Questocr] in August 2014. Under Mallinckrodt, price increases on Acthar have averaged in the low single digits."

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[33] https://www.aging.senate.gov/press-releases/collins-mccaskill-release-committee-report-of-bipartisan-drug-pricing-investigation
[34] *Id.*
[35] *Id.*
[36] NY Times: Stop Price Hikes.

553. Each of these statements was false and misleading when made. As such forth above, Mallinckrodt has all of the same characteristics of the companies studied, including having acquired a 1953 orphan drug which cost $40, and raised the price to over $40,000 after it implemented a closed distribution system in 2007 with Express Scripts. This closed distribution system has been controlled exclusively by Mallinckrodt since 2007 through contracts with Express Scripts and its subsidiary companies, which contracts Mallinckrodt renewed after August 2014 without changing the distribution system or lowering the price. In fact, it is believed and therefore averred that Mallinckrodt has raised the prices of Acthar, at least for adult indications, by double-digit percentages since 2014.

554. These misrepresentations were made in order to permit Mallinckrodt to maintain its "hedge fund model of drug pricing" initially implemented by Questcor in 2007 in conjunction with Express Scripts. The reason Mallinckrodt has continued to misrepresent the truth and deceive the public, especially payors like Local 322 – that is, Mallinckrodt's motive for lying and deceiving -- is because Acthar accounted for 34% percent of the company's $3.381 billion in net sales (or $1.15 billion) in 2016. That share has only increased in later years, making Acthar a critical part of Mallinckrodt's total revenue.

555. Mallinckrodt acknowledged the risk it faces it if were to tell the truth. In its annual report it conceded "if legislative or regulatory action were taken or insurers changed their reimbursement practices to limit our ability to maintain or increase the prices of our products, our future revenue and profitability could be negatively affected."

556. Mallinckrodt continues to misrepresent the value of Acthar as a treatment option for adult indications for which there are other, less expensive options, in order to maintain their shared unlawful profits from sales of Acthar. They do this because certain payors have started to

question Acthar's value and to take the steps to limit Acthar, as feared.

557. For instance, a July 2016 policy from UnitedHealthcare, the nation's largest third party payor covering New Jersey beneficiaries, determined that Acthar is more expensive than alternatives that are likely to produce equivalent results. Therefore, UnitedHealthcare determined that the drug "is unproven and not medically necessary" for all but three of the indications on the label."

558. Nevertheless, Mallinckrodt continues to mandate that physicians certify on the ASAP form that Acthar is "medically necessary" for a host of adult diseases, including all of the following beyond infantile spasms: ankylosing spondylitis, anterior scleritis, anterior segment inflammation, chorioretinitis, choroiditis, dermatomyositis, iridocyclitis, iritis, keratitis, multiple sclerosis, optic neuritis, panuveitis, polymyositis, proteinuria in nephrotic syndrome (with various etiology), posterior segment inflammation, psoriatic arthritis, rheumatoid arthritis, sarcoidosis, scleritis, systemic lupus erythematosus, uveitis and even some "other diagnosis" the physician might choose to list.

559. This list has grown on Mallinckrodt's watch. In 2011, the ASAP form utilized by Mallinckrodt with UBC listed just three indications: infantile spasms, multiple sclerosis and nephrotic syndrome. In other words, contrary to its public statements that Acthar does not "serve a small market, which would make unattractive to competitors", the "market" for Acthar has only been grown by Mallinckrodt's desire for greater profits. The drug "is unproven and not medically necessary" for the vast majority of disease states for which it is marketed and sold.

Scrutiny of Mallinckrodt's Unsubstantiated Claims of Superior Medical Efficacy And Mallinckrodt's Efforts to Conceal the Truth about Acthar's Lack of Efficacy for Adult Indications in the Face of Such Scrutiny.

560. In 2013, the federal military's health system, Tricare, saw a dramatic rise in

Acthar prescriptions, to 725 prescriptions at a cost of $34.4 million (before rebates). A Defense Health Industry spokesman said, "there is little supportable evidence" that Acthar is effective beyond the treatment of infantile spasms. As a result, Tricare restricted Acthar's use to infantile spasms, and the prescriptions dropped significantly the following year.[37]

561. Similarly, Aetna's national medical director for pharmacy and policy strategy explained why Aetna decided to restrict access to Acthar as follows: Mallinckrodt's "combination of aggressive marketing and aggressive price increases finally caused it to become a line item that a finance guy looked at and said: 'What the hell are we paying for this? Why? What is it?' And that's when we started looking at what's our policy around this stuff."

562. In 2012, Aetna reimbursements made up about 5% of Mallinckrodt's revenue. In September 2012, Mallinckrodt's stock dropped almost 50% after Aetna announced it had limited reimbursement of Acthar because it was not proven to be more effective than other treatments available.

563. Similarly, in March 2014, Mallinckrodt's stock dropped almost 30% after Citron Research release a report entitled, "Questcor is Deceiving FDA and Investors". Citron did its own private study of Acthar and found some of the active ingredients listed on the bottle to be disproportionate and/or inaccurate compared to Citron's tested Acthar samples. Citron pointed out that Mallinckrodt removed "Highly Purified" from the description in its recent 10K.

564. On January 18, 2013, Mallinckrodt decided to purchase the contract manufacturer, BioVectra Inc. of Charlottetown, Prince Edward Island, Canada. BioVectra had been the only supplier of Acthar Active Pharmaceutical Ingredient ("API") since 2003, when began to transition its supply of Acthar API from Aventis to new contract manufacturers. With

[37] https://www.propublica.org/article/the-obscure-drug-with-a-growing-medicare-tab

the acquisition of BioVectra, Mallinckrodt now controlled the supply of Acthar and the secrets behind the Acthar API. This was important to Mallinckrodt to protect its misrepresentations about Acthar safety and efficacy. It was also important to protect Mallinckrodt's antitrust monopoly power over Acthar, by being able to deny potential competitors the necessary samples of Acthar API needed to apply to the FDA for approval of a generic competitor to Acthar.

565. Acthar is not patented. That means anyone could manufacture it. But, only Aventis manufacturing Acthar for Mallinckrodt in 2001. So, by purchasing BioVectra, Mallinckrodt was able to remove from the market the only contract manufacturer of its non-patented, flagship product for which it was charging exorbitant prices without evidence through clinical trials of safety and efficacy for most adult indications.

566. In July 2003, Mallinckrodt transferred the Acthar final fill and packaging process to Chesapeake Biological Laboratories of Baltimore, Maryland ("Chesapeake"). Chesapeake became Cangene biopharma, Inc. This transfer was approved by the FDA in January 2004. Mallinckrodt maintained a contract relationship with Chesapeake/Cangene for fill and packaging through 2018.

567. In 2005, the FDA approved the further transfer of the manufacturing process of the Acthar API and two bioassays to BioVectra from ZLB Berhring, the successor of Aventis (the original seller of Acthar to Mallinckrodt), now known as CSL Behring. As Questcor's Vice President of Manufacturing, Dave Madeiros stated at the time, "FDA approval of the Acthar API manufacturing transfer accomplishes a major goal that was established when this product [Acthar] was acquired."

568. Only the Acthar potency bioassay remained to be transferred as of 2005. However, according to a 2014 investor presentation, the potency bioassay was transferred to

Emergent Biosolutions of Gaithersburg, Maryland.

569. As explained by Dr. Gary Phillips in October 2014, the then Executive Vice President and Chief Strategy Officer of Mallinckrodt Pharmaceuticals, and Senior Vice President and President of Mallinckrodt's Autoimmune and Rare Disease Business, the manufacturing and distribution process as of 2014 worked like this:

a. the Acthar API is bio-extracted from the pituitary gland of a pig at the BioVectra facility, wholly owned by Mallinckrodt.

b. The API is then moved to a third-party manufacturer called Emergent BioSolutions who takes the active pharmaceutical ingredient and puts into its final form.

c. At both stages, potency testing is done by CSL Behring.

d. The final product is transferred to Mallinckrodt's specialty distributor, CuraScript, who ships it directly to patients

570. In its 2013 10K, Mallinckrodt conceded that, since 1962, with the passage of the Drug Efficacy Act, prescription drugs needed to present evidence of safety and efficacy via clinical trials in order to be marketed and sold as safe and effective for the indicated uses. However, because Acthar was originally approved in 1952, no evidence of Acthar's safety or efficacy in the form of clinical trials existed or was presented, except for IS and MS indications.

571. Consequently, Mallinckrodt has sought to convince the medical community, patients and payers that "evidence as to safety and efficacy is not limited to clinical trials. Evidence can come in other forms such as prospective clinical datasets generated by third parties through independent clinical trials and case series or retrospective case reviews involving a small number of patients."

572. Mallinckrodt conceded that "[t]he approved indications for which Acthar is promoted and which generate a significant amount of the Company's revenues typically include

clinical evidence of this type."

573. In other words, Acthar generates more revenue from high prices charged for adult indications for which there is no evidence from clinical trials demonstrating safety and efficacy, as has been required by the FDA since 1962. This "significant amount of the Company's revenues" is due to Mallinckrodt/Questcor's promotion of Acthar based upon anecdotal "evidence" from "case reviews involving a small number of patients."

574. That is why Mallinckrodt's marketing efforts with doctors has been so important. As Mallinckrodt concedes, "[h]ealthcare provider understanding of Acthar is facilitated by our experienced team of sales representatives and managers." Thus, the few hundred doctors whom Mallinckrodt pays as "consultants" and "speakers", and who generate "case reviews" of their own experience using Acthar with patients for Mallinckrodt's promotional use, generate the vast majority of Acthar prescriptions paid for by payors, like Local 322.

MALLINCKRODT'S PATTERN OF MISREPRESENTATIONS AND DECEPTIONS ABOUT THE VALUE OF ACTHAR

Misrepresentation and Deception Continues in 2018

575. Even as late as 2018, Mallinckrodt has continued to misrepresent the purported value of Acthar, the reasons for and size of its price increases, and its refusal to bring Synacthen to market prior to the FTC mandate to do so.

576. In a statement released June 29, 2018, titled "H.P. Acthar Gel Value to Patients", Mallinckrodt claimed to be responding to "[a] number of media outlets and other external parties [who] have made misleading and inaccurate allegations about H.P. Acthar Gel … and Mallinckrodt. It is important to set the record straight." Significantly, Mallinckrodt was responding in the press to "the allegations contained in the City of Rockford Illinois complaint".

577. But rather than tell the truth, Mallinckrodt only compounded its prior

misrepresentations and deception by making the following further misleading and deceptive statements.

578. With regard to the price of Acthar, Mallinckrodt states the price is "$38,892, before discounts provided to payors." This is misleading and deceptive in two respects. First, payors have been charged more than twice that price for Acthar for adult indications. Second, Mallinckrodt provides no "discounts to payers". Instead, payors, like Local 322, are forced to pay the inflated AWP-based price established between Mallinckrodt and Express Scripts. It is believed and therefore averred that the price Mallinckrodt charges Express Scripts for the Acthar its ships to its plan sponsors' beneficiaries, as in the case of Local 322, is far less than the AWP-based prices charged to payers.

579. Mallinckrodt also reiterated its claims that, "[s]ince acquiring the drug in late 2014, Mallinckrodt has only made modest price adjustments in the mid-single digit percentage range."

580. Mallinckrodt misrepresented its reasons for implementing the exclusive distribution system and the reasons why "reimbursement has stayed constant". In 2014, Mallinckrodt stated that "our predecessor company established a strong foundation" a support network which was established to help patients with the reimbursement process, with a primary focus on appropriate access and accelerated reimbursement time so patients get the product when they need it."

581. But, when the FDA rejected Mallinckrodt's hospital consignment plan, Mallinckrodt stated the reason they needed it was because the existing distribution system made it difficult to get Acthar in time.

MALLINCKRODT REWARDS DOCTORS WHO PRESCRIBE ACTHAR AND ACT AS SPOKEPERSONS IN THE KICKBACK SCHEME INTENDED TO CAUSE PAYORS TO OVERPAY FOR ACTHAR THROUGH MISREPRESENTATIONS AND DECEPTION ABOUT THE PURPORTED VALUE OF ACTHAR IN RELATION TO OTHER TREATMENT OPTIONS

582. "According to the Medicare Drug Spending Dashboard for 2015," Acthar "was the single most expensive drug, per patient, that the government paid for" in 2015.[38]

583. Of the 3,100 Medicare patients that received Acthar in 2015, the average cost per patient to the program was $162,371.[39] Total Medicare spending on Acthar alone, was $504 million, which represented a 29% increase from 2014 and was up from $49.5 million in 2011.[40]

584. In 2008, Acthar ranked around 660th out of the more than 3,000 drugs prescribed in Medicare in terms of total cost. By 2012, it ranked 139th. By 2015, it was number one.

585. During the period 2013 – 2016, Medicare spending on Acthar was nearly $1.8 billion.[41]

586. How did Medicare spending on a 65 year-old medication increase by so much? The increase in Medicare spending coincided with a marketing push by Mallinckrodt to target doctors treating adults, especially seniors, with rare conditions included in the 19 indications approved in 1952. Specifically, Mallinckrodt engaged in a kickback scheme designed to incentivize doctors to prescribe Acthar for all sorts of adult disease states, despite the availability of cheaper, equally or more efficacious alternatives.

587. In 2014, the top fifteen (15) prescribers of Acthar to Medicare patients accounted for 10 percent of the total Medicare Acthar prescriptions, an unusually high proportion.

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[38] https://www.nytimes.com/2016/12/23/business/drug-price-medicare-mallinckrodt-acthar.html ("NY Times: "Stop Price Hikes")

[39] *Id.*

[41] https://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html

588. The volume of prescriptions written by these few prescribers shows that Acthar was not being prescribed for the limited use, rare conditions for which it was approved. Instead, it has been marketed by Mallinckrodt as a maintenance medication to replace other proven, long-term treatments.

589. In 2014, Mark Trudeau admitted to investors that Acthar "is a product that is used for rare disease. So consequently, any individual doctor may only see one patient or two a year that is even a candidate for Acthar. So it is not surprising that you have some physicians that in a given year will treat a patient; another year mightn't, because they just don't see that patient… If we look at the active prescribers, about 3,000 [doctors treating] 9,000 patients; three on average. But of course there is a lot of variability there. …With the type of the disease, the rareness of the disease, the fact that Acthar is typically used for patients that are pretty far down the treatment paradigm, the actual available patient population for any individual physician is going to be pretty low."

590. But the truth is, the numbers of patients treated by the doctors whom Mallinckrodt has targeted is extraordinarily high – dozens of patients receiving year-round treatments with Acthar at annual cost to payers of hundreds of thousands of dollars.

591. ACTH is steroids. Steroids are cheap. Therefore, Acthar should be cheap, as it was in 2001. But it is not.

592. Mallinckrodt's pricing scheme has changed that. Its marketing scheme to target doctors through kickbacks had ensured Acthar is prescribed. Its exclusive distribution scheme with Express Scripts has ensured there is no impediment to getting the patient on the medication, and keeping the patient on the medication. And through its Express Scripts "hub", Mallinckrodt ensures that Acthar is paid for – reimbursement remains constant.

593. In 2016, more than 80% of the doctors who filed Medicare claims for Acthar received money or other perks from Mallinckrodt.[42]

594. From 2013 through 2015, Mallinckrodt has made 121,013 individual payments to physicians related to Acthar totaling over $19.53 million.

595. According to ProPublica, one nephrologist, Ana Stankovic has received $147,000 in payments between 2013 and 2015, helping her to be the most often-paid physician by pharmaceutical companies.[43]

596. A 2014 investigation by ProPublica revealed that in 2012, only eighteen (18) physicians wrote more than fifteen (15) prescriptions of Acthar for reimbursement by Medicare. Half of these physicians, and the top four (4) prescribers "were promotional speakers, researchers or consultants for Questcor."[44]

597. At least two Acthar physician-speakers, have resolved criminal or civil prosecution by the federal government for healthcare fraud.[45] Dr. Gavin Awerbuch, "the most frequent prescriber of the drug in 2011" was charged in 2014 with "defrauding Medicare of $1.9 million and Blue Cross Blue Shield $1.2 million" and plead guilty on November 7, 2016 to health care fraud.46 In 2011, he was the most frequent prescriber of Acthar for Medicare

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[42] *Id*.

[43] *See* https://projects.propublica.org/docdollars/doctors/pid/362632 *;* https://projects.propublica.org/docdollars/.

[44] https://www.propublica.org/article/top-acthar-prescribers-in-medicare-have-ties-to-its-maker.

[45] *Id*.

[46] http://www.detroitnews.com/story/news/local/oakland-county/2016/11/07/doc-coin-collection/93446828/.

patients.[47]

598. By rewarding physicians for maintaining the market for Acthar, Mallinckrodt has continued to foster sales of the product at its inflated prices.

599. But Mallinckrodt has even sought to deceive the public about such payments, which the government mandated in 2014 as part of its Open Payments database intended to bring transparency to relationships between drug companies and doctors. The Physician Payment Sunshine Act, a part of the 2010 Affordable Care Act, mandated that all drug and device companies report payments to doctors.

600. But, Mallinckrodt has routinely sought to mislead and deceive the public, including payors like Local 322, by willfully misspelling the product name for H.P. Acthar, reporting its payments to doctors under two separate companies, Mallinckrodt LLC and Questcor, and spreading its payments out in small increments over time.

601. Between August 2014 (when Mallinckrodt acquired Questcor) and December 2016, Mallinckrodt LLC reported paid doctors $15.5 million as Acthar speakers and consultants, nearly half the total amount paid for Mallinckrodt's entire product line consisting of more than 30 products. Although Questcor ceased to exist after it was acquired by Mallinckrodt in August 2014 – its name was legally changed to Mallinckrodt ARD -- Mallinckrodt continued to report payments to doctors through 2016 as being made by Questcor. The total of these payments was $12.2 million. In other words, Mallinckrodt concealed the total of its $27.9 million in payments to doctors in just over three (3) years by willfully reporting $12.2 million under a defunct company name.

602. In order to further conceal its payments to doctors, Mallinckrodt scattered the

[47] https://www.propublica.org/article/top-acthar-prescribers-in-medicare-have-ties-to-its-maker.

information. It logged its payments related to Acthar under at least eight (8) different names, including Acthar, Acthar-Pulm, Acthar-IS, Acthar-Rheum, and Acthar-MS, among others. By willfully scattering its payments through such misreporting, the payments associated with each name did not stand out. But, when the payments were added together, Acthar ranked among the top 20 drug companies for spending on doctors.

603. Another way Mallinckrodt sought to conceal its payments to doctors for Acthar prescriptions has been by paying small amounts multiple times a year. For instance, in the case of Dr. Ana Stankovic of Danvers Massachusetts, she received payments from drug companies in 2014 totaling nearly $600,000. She received a payment from a drug company on 242 of 365 days in that calendar year. Mallinckrodt paid Dr. Stankovic, $476,000 between August 2013 and December 2016. In 2016, Mallinckrodt paid Dr. Stankovic $124,000 in over 250 separate installments ranging from $2 to $5,900. On 36 separate occasions in 2016 alone, Mallinckrodt paid Dr. Stankovic between $1,500 - $5,900 for promotional speaking or consulting.

604. These actions by Mallinckrodt were willful and intended to misrepresent and deceive patients and payors about Mallinckrodt's payments to doctors to prescribe its high priced medication, despite the lack of proven medical efficacy or value for what was being charged. By making doctors their partners in the scheme, Mallinckrodt has been able to influence, if not override, the independent medical judgment of physicians, cultivating promotional advocates for its high priced medication through a campaign of money funding a scheme of misrepresentations and deception.

COUNT I
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS
LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
New Jersey Consumer Fraud Act

605. Plaintiff hereby incorporates by reference the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein, and further alleges as follows.

606. The New Jersey Consumer Fraud Act, N.J. Stat. § 56:8-1, et seq. ("NJCFA"), provides that the "act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice."

607. The unconscionable and deceptive acts and practices described herein are declared unlawful under the NJCFA.

608. The NJCFA authorizes any person, including "any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestuis que trustent thereof" to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and ameliorate the unfair and deceptive conduct described herein.

609. Local 322 is a person pursuant to the NJCFA. Local 322 has been injured as a result of the Defendants' unconscionable, unfair, and deceptive conduct in violation of the

NJCFA, and hereby seeks damages.

610. The acts and circumstances described herein demonstrate that Mallinckrodt, Cigna/Express Scripts and Pratta acted unlawfully within the meaning of the NJCFA such that Local 322 and the Class may be awarded up to three times the actual damages sustained, and such additional relief as deemed necessary or proper.

611. Local 322 seeks relief against all Defendants for their unconscionable commercial practices with regard, inter alia, their scheme to raise and fix the prices of Acthar to supracompetitive levels, maintain and enhance Mallinckrodt's monopoly power in the ACTH market, and to promote Acthar with a mode of action that is unknown, for uses and doses that are not FDA-approved..

612. Mallinckrodt created restrictions on trade and commerce through the creation of the exclusive arrangement for Acthar.

613. Mallinckrodt raised the prices of Acthar, with Cigna/Express Scripts.

614. As described herein, Mallinckrodt and Cigna/Express Scripts agreed to maintain the supracompetitive prices of Acthar through the ASAP Program, limiting distribution of the drug and stifling the ability of a competitor to enter the ACTH market. Further, to maintain these supracompetitive prices, Mallinckrodt acquired Synacthen. This unconscionable conduct caused Local 322 to pay prices for Acthar significantly greater than in a competitive market. Through the conduct of sales representatives like Pratta TPPs like Local 4322 were forced to overpay for Acthar. Therefore, Local 322 is entitled to relief under the NJCFA.

615. Defendants are engaging in unconscionable commercial practices in trade or commerce that directly or indirectly harmed consumers in New Jersey, like Local 322 and the Class, within the meaning of the NJCFA.

616. By engaging in the acts and practices set forth above, Defendants' conduct constitutes unconscionable commercial practices, deception, fraud, false pretenses, false promises, misrepresentations, or the knowing, concealment, suppression, or omission of material facts with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of merchandise, in violation of the NJCFA.

617. Defendants willfully engaged in such practices, knowing them to be unconscionable, unfair, and deceptive or with reckless disregard for how their deception would impact Local 322. Defendants intended and/or expected that payors, including Local 322, would pay prices for Acthar significantly greater than in a competitive market, to their substantial detriment.

618. The wrongful conduct and unconscionable, unfair, and deceptive commercial practices alleged in this Complaint have occurred, and continue to occur, in the ordinary course of Defendants' businesses or occupations, and have caused great harm to payors like Local 322 who were foreseeable and direct victims.

619. Local 322 was injured as a direct and proximate result of Defendants' conduct in violation of New Jersey law and hereby seek declaratory and junctive relief and damages.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against all Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT II
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS
LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
New Jersey Antitrust Act

620. Plaintiff hereby incorporates by reference the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein, and further alleges as follows.

621. Local 322 may maintain state antitrust claims against all Defendants. Local 322 seeks relief as allowed under New Jersey antitrust law and is allowed to seek an injunction against Defendants for their anticompetitive conduct to prevent it from continuing, and recurring.

622. Under the statutory and decisional law of New Jersey, Local 322 is also permitted to seek damages against Defendants.

623. The New Jersey Antitrust Act, N.J. Stat. § 56:9-1, et seq. ("NJAA"), makes unlawful "[e]very contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce, in this State". The NJAA also provides that, "[i]t shall be unlawful for any person to monopolize, or attempt to monopolize, or to combine or conspire with any person or persons, to monopolize trade or commerce in any relevant market within this State."

624. The unfair methods of competition and unfair trade practices described herein are declared unlawful under the NJAA.

625. The NJAA authorizes any person, including natural persons, corporations, partnerships, companies, trusts, or association of persons to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and ameliorate the anticompetitive conduct described herein.

626. Local 322 is a person as defined by the NJAA and therefore may institute proceedings for injunctive relief, temporary or permanent, against threatened loss or damage to its property or business by a violation of the NJAA. Local 322 has been injured as a result of the Defendants' conduct in violation of the NJAA and hereby seeks damages.

627. The acts and circumstances described herein demonstrate that all Defendants acted unlawfully within the meaning of the NJAA such that Local 322 and the Class may be awarded up to three times the actual damages sustained, and such additional relief as deemed necessary or proper.

628. Local 322 seeks relief against Defendants for their scheme to raise and fix the prices of Acthar at supracompetitive levels, and to maintain Mallinckrodt's monopoly power in the ACTH market.

629. Defendants created restrictions on trade and commerce through the creation of their exclusive arrangements for Acthar.

630. Mallinckrodt and Cigna/Express Scripts agreed in writing to raise the prices of Acthar to supracompetitive levels.

631. As described herein, Mallinckrodt and Cigna/Express Scripts agreed to maintain the supracompetitive prices of Acthar through the ASAP Program, limiting distribution of the drug and stifling the ability of a competitor to enter the ACTH market. Further, to maintain these supracompetitive prices, Mallinckrodt acquired Synacthen, and then kept it off the market with Cigna/Express Scripts express or implied consent. Pratta then marketed and sold Acthar at these inflated prices, to the detriment of New Jersey patients and their TPPs. This conduct caused Local 322 and the Class to pay prices for Acthar significantly greater than in a competitive market. Therefore, Local 322 is entitled to relief under the NJAA.

632. Local 322 was injured as a direct result of the Defendants' conduct in violation of New Jersey law and hereby seek damages.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against all Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT III
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS
LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
VIOLATION OF NJ RICO, N.J.S.A. § 2c:41-2(c)

633. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows:

634. Mallinckrodt, Cigna/Express Scripts (including its subsidiaries UBC, Accredo and CuraScript), and Pratta are each "persons" within the meaning of the New Jersey RICO statute who each conducted the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity in violation the New Jersey statute. Plaintiff and the members of the Class are also persons.

635. The Acthar Marketing Enterprise is an association in fact enterprise affecting interstate commerce consisting of (i) Mallinckrodt, and its MSLs and sales representatives, (ii) Cigna/Express Scripts and its subsidiaries, including UBC and its RSs, Accredo and its pharmacists, and CuraScript and its employees, (iii) sales representatives like Pratta, and (iv) KOLs, both named and unnamed in this Complaint. At all relevant times, Mallinckrodt, Cigna/Express Scripts, Pratta, the KOLs and other co-conspirators conducted the affairs of an association-in-fact enterprise including their directors, employees, and agents who assisted in

carrying out their alleged scheme.

636. The Acthar Marketing Enterprise consists of a group of "persons" associated together for the common purpose of promoting Acthar for off-label uses and doses, with messages of an unknown mode of action, and earning profits therefrom.

637. Mallinckrodt and Cigna/Express Scripts, along with Pratta and others like her, have conducted and participated in the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity, which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by Defendants throughout the Class Period number in the thousands, and Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period, a period which began in 2007 and continues through the present.

638. This enterprise was manifested by and through the ASAP program, but was made up of the three components of the alleged scheme: the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Accordingly, the enterprise concerned the marketing and sale of Acthar pursuant to the 2007 new strategy with each of these components described herein.

639. The Acthar Marketing Enterprise was begun in 2007, and is an ongoing and continuing business organization consisting of both corporations (i.e., Mallinckrodt and Cigna/Express Scripts) and individuals (Pratta, MSLs, RSs, KOLs), associated for the common purpose of distributing, pricing and marketing Acthar to Plaintiff and the Class at exorbitant AWP prices, for unapproved uses and doses, and deriving substantial profits from these activities.

640. The Acthar Marketing Enterprise engages in and affects interstate commerce

because it engages in the following activities across state boundaries: the distribution, pricing, marketing, sale, and/or purchase of Acthar, the transmission of WAC and AWP pricing information to the pricing compendia, ASAP program literature (including the Acthar Start Form at Exhibit "A" hereto), the operating of the ASAP program website, communications with providers, patients and TPPs by UBC as part of ASAP, and the transmission and/or the receipt of invoices and payments related to the prescription and use of Acthar. Through these activities the Acthar Enterprise markets, distributes and sells Acthar to thousands of individual patients, including those receiving prescription drug benefits from the Plaintiff and the Class.

641. The Acthar Marketing Enterprise has functioned as a continuing unit, as evidenced by the continuing coordination of activities between and among Defendants. There is a common communication network by which Mallinckrodt (and Pratta) and Cigna/Express Scripts (and their subsidiaries, agents and employees, including MSLs, RSs and KOLs) shared and continue to share information on a regular basis for all times relevant to this lawsuit, but beginning at least in 2007 and continuing through the present. Typically, this communication occurred by use of the wires and mails, in which Defendants and KOLs all agree to charge TPPs inflated AWP prices for Acthar to the patients of TPPs, like Local 322, and other Class members. These entities functioned as a continuing unit for the purposes of implementing the scheme to inflate the prices of Acthar by and through ASAP. When issues arose during the scheme, each agreed to take actions to hide the scheme and to continue its existence.

642. Mallinckrodt has exerted control over the Acthar Enterprise, has associations with the Enterprise, and has directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

a. Mallinckrodt has directly controlled the AWP price at which Plaintiff and the Class purchase Acthar;

b. Mallinckrodt has directly controlled the AWP price at which Plaintiff and the Class reimburse for Acthar;

c. Mallinckrodt has directly controlled the ASAP program materials and website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Defendants to conduct their unconscionable and unfair pricing of Acthar;

d. Mallinckrodt has directly controlled the exclusive distribution network for Acthar through the ASAP Enterprise;

e. Mallinckrodt has relied on their employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires;

f. Mallinckrodt placed their own employees and agents in positions of authority and control over the Acthar Marketing Enterprise;

g. Mallinckrodt controlled the content of the messages being delivered by the Acthar Marketing Enterprise at each seminar, event, and presentation, in the publications being used and presented, in the direct communications with providers, patients and payors, all of which included misinformation and false and misleading statements about the safety, efficacy, effectiveness, usefulness, and value of Acthar for off-label uses;

h. Mallinckrodt has participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices;

i. Mallinckrodt has selected and approved physicians to serve as KOLs, who in turn work with UBC under the ASAP to deliver off-label prescriptions of Acthar for payment by TPPs; and

j. Mallinckrodt worked to ensure that the Acthar prescribed by KOLs and other providers were paid for by TPPs at the inflated AWPs charged by them.

643. Cigna/Express Scripts has exerted control over the Acthar Enterprise, has associations with the Enterprise, and has directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

a. Cigna/Express Scripts has directly controlled the AWP price at which Plaintiff and the Class purchase Acthar;

b. Cigna/Express Scripts has directly controlled the AWP price at which Plaintiff and the Class reimburse for Acthar;

c. Cigna/Express Scripts has directly controlled the ASAP program materials and website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Defendants to conduct their unconscionable and unfair pricing of Acthar;

d. Cigna/Express Scripts has directly controlled the exclusive distribution network for Acthar through the ASAP Enterprise;

e. Cigna/Express Scripts has relied on their employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires;

f. Cigna/Express Scripts placed their own employees and agents in positions of authority and control over the Acthar Marketing Enterprise;

g. Cigna/Express Scripts controlled the content of the messages being delivered by the Acthar Marketing Enterprise at each meeting, seminar, event, and presentation, in the publications being used and presented, in the direct communications with providers, patients and payors, all of which included misinformation and false and misleading statements about the safety, efficacy, effectiveness, usefulness, and value of Acthar for off-label uses;

h. Cigna/Express Scripts has participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices;

i. While Mallinckrodt has selected and approved physicians to serve as KOLs, who in turn work with Cigna/Express Scripts' UBC under the ASAP to deliver off-label prescriptions of Acthar for payment by TPPs; and

j. Cigna/Express Scripts worked to ensure that the Acthar prescribed by KOLs and other providers were paid for by TPPs at the inflated AWPs charged by them.

644. Pratta has exerted control over the Acthar Enterprise, has associations with the Enterprise, and has directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

k. She has directly controlled the AWP price at which Plaintiff and the Class purchase Acthar, by promoting the prescription and sale of Acthar at such price, and the reimbursements by TPPs at that price;

l. She has directly controlled the AWP price at which Plaintiff and the Class reimburse for Acthar;

m. She has directly controlled the dissemination of ASAP program materials and access to the website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Defendants to conduct their unconscionable and unfair pricing of Acthar;

n. She has controlled the content of the messages being delivered by the Acthar Marketing Enterprise at each meeting, seminar, event, and presentation she attended, in the publications being used and presented by her at such meetings, in the direct communications she had with providers, patients and payors, all of which included misinformation and false and misleading statements about the safety, efficacy, effectiveness, usefulness, and value of Acthar for off-label uses;

o. She has participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices;

p. She has assisted Mallinckrodt in selecting and approving physicians to serve as KOLs, including Dr. Papa-Rugino, who in turn work with Cigna/Express Scripts' UBC under the ASAP to deliver off-label prescriptions of Acthar for payment by TPPs; and

q. She has worked to ensure that the Acthar prescribed by KOLs and other providers were paid for by TPPs at the inflated AWPs charged by them.

r. She directly promoted the use of improper co-pay assistance through CDF in order to ensure that TPPs paid the inflated price of Acthar for unapproved doses in the treatment of MS patients.

645. Thus, all Defendants have conducted and participated in the affairs of the ASAP Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1345, relating to wire fraud. Defendants' pattern of racketeering activity likely involved hundreds, if not thousands, of separate instances of the use of the United States mail, private shipping services, facsimiles, or interstate wires, including the internet, in furtherance of its fraudulent and unlawful scheme. Each of these fraudulent

mailing and interstate wire transmissions separately constitutes a "racketeering activity". Collectively, these violations constitute a "pattern of racketeering activity" in which the Defendants intended to defraud Plaintiff and members of the Class.

646. As described in greater detail herein, Defendants' fraudulent scheme consisted of confining patients to an exclusive distribution network, such that they could drastically inflate the prices charged for Acthar. By conducting this program through the mail and wires, Defendants engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

647. As detailed above, the Acthar Marketing Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Acthar was safe and effective so the Plaintiff and the Class Members paid for this drug at inflated prices to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, useful and valuable; (b) presenting seminars, events, in-person meetings and telephonic communications misrepresenting the off-label uses of Acthar for which Defendants knew Acthar was not proven to be scientifically safe, effective, useful or valuable to physicians and other healthcare providers; (c) disseminating materials created pursuant to the Acthar Marketing Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Acthar was safe, effective, useful and valuable; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, usefulness and value of Acthar to treat conditions for which it had not been approved by the FDA.

648. These racketeering activities amounted to a continuing course of conduct, with similar pattern and purpose, intended to harm Plaintiff and the Class to pay excessive amounts for Acthar. Each instance of racketeering activity perpetuated by Defendants was related, and

had a similar intended purpose, involved similar participants and methods of execution, and have the same results affecting the same class of victims, including Plaintiff and the Class. Defendants had engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Acthar Marketing Enterprise.

649. Defendants' pattern of racketeering activities alleged herein are separate and distinct from each other.

650. Defendants' pattern of racketeering activities had directly and proximately caused Plaintiff and members of the Class to be injured in their property insofar as Plaintiff and members of the Class have overpaid thousands of dollars in inflated reimbursements and other payments for Acthar. Plaintiff's and the Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening forces; their injuries were a foreseeable and natural consequence of the Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with potentially different standing or levels of injury because there are no other injured parties besides Plaintiff and the TPP Class Members in this case, who are the parties directly injured by the Defendants' RICO violations. No one other than Plaintiff and the Class could vindicate the rights and claims of Plaintiff and the Class.

651. By virtue of these violations, Defendants are liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the costs of this suit, including reasonable attorney's fees.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief

deemed just and appropriate by this Court.

COUNT IV
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS
LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
CONSPIRING TO VIOLATE NJ RICO, N.J.S.A. 2C:41-2d

652. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

653. Section 2C:41-2d of New Jersey RICO provides that it "shall be unlawful for any person to conspire as defined by N.J.S. 2C:5-2, to violate any of the provisions of this section."

654. Defendants violated this section by conspiring to associate with a racketeering enterprise. Mallinckrodt knowingly joined Cigna/Express Scripts [and its subsidiaries] and Pratta, and they in turn joined with Mallinckrodt and others in a conspiracy to inflate the prices of Acthar and market the off-label uses and doses of Acthar using misleading and deceptive messages described herein about the mode of action, efficacy, value and benefits of Acthar.

655. The object of this conspiracy is to and has been to conduct or participate in, directly or indirectly, the conduct of the affairs of the Acthar Marketing Enterprise described herein, through a pattern of racketeering activity that directly cause injury to the business or property of Plaintiff and the Class. The corporate defendants conspired with, *inter alia*, the sales representatives (like Pratta), MSLs, RSs, KOLs and others to promote Acthar and suppress information about the harms know to result from Acthar use.

656. Defendants and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering activities in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class of money.

657. That Defendants knew and adopted the criminal purpose of the Enterprise is

evident from its own documents and public statements of its officers. Defendants' communications reflect an express illegal agreement between and among themselves and others to form and operate the ASAP in furtherance of the Acthar Marketing Enterprise. The Corporate Defendants' officers stated that it was this agreement in 2007 that was the hallmark of a new strategy to increase revenues and profits.

658. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of a violation of RICO by conspiring to violate RICO, but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity. In other words, Defendants adopted the goal of furthering or facilitating the conspiracy, and was aware of the essential nature and scope of the Acthar Marketing Enterprise and intended to participate in it.

659. Additionally, Defendants' conduct in sending e-mails, faxes and other communications to each other to direct the distribution and sale of Acthar through ASAP is consistent with the existence of an agreement to carry out the scheme to inflate prices and maximize profits.

660. Defendants actively furthered the goals of the Acthar Marketing Enterprise to defraud end payors, like Plaintiff and the Class. They changed the distribution scheme for Acthar with the intention that the changes would allow the Pricing Scheme to be effectuated; engaged in frequent discussions with between each other about the plan to raise Acthar prices and to promote the sale of Acthar at these new high prices for unapproved uses and doses in the marketplace; and communicated with KOLs and other providers about the same.

661. Defendants sought to and have engaged in the commission of and continue to

commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

662. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue.

663. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid millions of dollars in overpayments for Acthar that they would not have paid had the Defendants not conspired to violate New Jersey RICO.

664. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by Defendants' racketeering activity as described above. As also set forth above, these injuries would not have occurred but for Defendants' RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

665. Patients, physicians, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of Defendants and the Acthar Marketing Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the necessity, approval and safety of Acthar as promoted by Defendants. Because Defendants controlled all knowledge upon which the claims of Acthar's necessity, approval and safety were based, all Class Members, as well as other members of the medical and consuming public were obligated to rely on Defendants' representations about Acthar. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical

information about Acthar.

666. As co-conspirators, all Defendants are jointly and severally liable for all damage that occurred as a result of its actions (and those of UBS and others) in furtherance of the conspiracy to raise prices of Acthar and market the sale of Acthar at inflated prices for unapproved uses and doses. Each Defendant is liable for all damages arising from each other's conduct in furtherance of the scheme.

667. By virtue of these violations, Defendants are liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

668. By reason of the foregoing, and as a direct and proximate result of the Defendants' fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

669. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against Defendants in a sum that exceeds the jurisdiction of all lower courts.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against all Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT V
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
Negligent Misrepresentation

670. Plaintiff hereby incorporates by reference the allegations within all preceding and

following paragraphs within this Complaint as if they were fully set forth herein, and further alleges as follows.

671. Defendants acts violate New Jersey common law against negligent misrepresentation.

672. In setting and selling at the prices for Acthar, which prices Local 322 paid, Defendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace.

673. These representations were material to the transactions at hand as Local 322 used and relied upon these prices as the amount to pay and/or reimburse for Acthar.

674. As set forth more fully above, these prices were artificial prices, unrelated to any actual, reasonable price in the marketplace, or actual value of Acthar, but created and manipulated by Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which Defendants knew or, in the absence of recklessness, should have known to be false.

675. Defendants made these false representations about the prices of Acthar with the intent of misleading Local 322 into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

676. Local 322 justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Defendants based on the price set by Mallinckrodt and Cigna/Express Scripts.

677. Local 322's contracts with Express Scripts provided for reimbursement of Acthar at AWP prices were prices set by Mallinckrodt with Cigna/Express Scripts. As such,

Mallinckrodt communicated these false prices directly to Local 322 for the Acthar sold.

678. As a direct and proximate result of the false representations of the Defendants as set forth above, Local 322 was harmed in that it was unaware of the artificial, inflated prices of Acthar, would not have paid and/or reimbursed the artificially inflated prices for Acthar had it known of the false representations and, in fact, overpaid for the Acthar because of the false representations.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against all Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VI
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS
LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
Conspiracy/Aiding and Abetting

679. Plaintiff hereby incorporates by reference the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein, and further alleges as follows.

680. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff, and continuing thereafter until the present, Mallinckrodt entered into an exclusive agreement and aided and abetted Pratta, Cigna/Express Scripts and its subsidiaries, KOLs and others to violate New Jersey law to defraud and deceive the Plaintiff by causing it to pay more for Acthar than it otherwise would have paid in the absence of Defendants' agreement and concerted action.

681. In the absence of Defendants' agreement and their aiding and abetting, Local 322

and the Class would not have paid as much as they paid for Acthar.

682. Pursuant to the unconscionable, unfair and deceptive scheme to distribute, market and sell Acthar to derive substantial profits, Defendants engaged in a wide range of activities, the purpose and effect of which was to deceive payors, including Local 322, and acted by aiding and abetting each other to raise prices and increase profits at the expense of payors like Local 322. Those acts of aiding and abetting include at least the following:

a. discussing and agreeing with others that they would directly control the price at which Local 322 paid for Acthar;

b. discussing and agreeing among themselves that they would increase the price at which Local 322 paid for Acthar;

c. discussing and agreeing with others that they would directly control the ASAP program materials and website which enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to conduct their unfair pricing scheme for Acthar;

d. discussing and agreeing with others that they would directly control the exclusive distribution network for Acthar through the ASAP Program;

e. discussing and agreeing with others that they would rely on employees to promote the ASAP Program through the marketing alleged herein, and through use of the mail and the wires;

f. discussing and agreeing with others that they would participate in the affairs of the ASAP program by using a fraudulent scheme to market and sell Acthar at inflated prices; and

g. discussing and agreeing with others that they would conceal and suppress the truth about the Acthar inflated prices, the monies earned from payors like Local 322, and their exclusive arrangement to maintain and enhance Mallinckrodt's monopoly power as alleged herein.

683. In addition to the specific facts set forth above, it is alleged Defendants engaged in meetings, among the purposes of which were to discuss the importance of controlling the direct distribution, marketing, sale and administration of Acthar to payors like Local 322 and aiding and abetting each other to derive substantial profits from these activities.

684. Defendants knowingly provided substantial assistance and encouragement to each other and aided and abetted each other to derive substantial profits by causing payors like Local 322 to pay inflated prices.

685. Defendants performed the acts set forth herein intending to injure payors of Acthar, like Local 322, by causing them to pay inflated prices so that Defendants all could derive substantial profits.

686. Mallinckrodt performed the acts alleged herein in furtherance of their agreement with intent and/or with knowledge of the injury and damage it would cause to payors like Local 322, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences.

687. As a direct and proximate result of Defendants' aiding and abetting as alleged herein, Local 322 has been injured and damaged, and Defendants are liable for such injuries and damages.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against all Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VII
UNITED ASSOCIATION OF PLUMBERS & PIPEFITTERS
LOCAL 322 OF SOUTHERN NEW JERSEY
v.
DEFENDANTS
Unjust Enrichment

688. Plaintiff hereby incorporates by reference the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein, and further alleges as follows.

689. This Count alleges unjust enrichment against Defendants.

690. Local 322's covered beneficiaries received direct shipments of Acthar from Defendants via their exclusive distribution mechanism established in 2007. In exchange for such Acthar, Local 322 made direct payments to Cigna/Express Scripts for the benefit of Mallinckrodt. Indeed, such payments were transferred by Cigna/Express Scripts to Mallinckrodt pursuant to an understanding between the two that the total amount would be forwarded to Mallinckrodt, less a certain amount previously agreed to by Mallinckrodt and Cigna/Express Scripts. The amount charged by Mallinckrodt for Acthar was the amount paid by Local 322 pursuant to its agreement with Cigna/Express Scripts.

691. Pratta received substantial bonuses from Mallinckrodt based on her success in effectuating the unlawful scheme alleged herein in New Jersey up through 2017. She also has been [or will be] paid substantial sums are part of a relators' share from suing Mallinckrodt.

692. Pratta, while employed by Questcor/Mallinckrodt, prosecuted a qui tam action referenced herein in detail and at length. While litigating that action, Pratta continued and implemented the same illegal schemes and conduct that she alleged against Mallinckrodt and was compensated in the form of bonuses, commissions and salary from Mallinckrodt.

693. Despite receiving compensation for furthering the illegal schemes and conduct of Mallinckrodt described herein, Pratta also sought the resolution of her own qui tam action against Mallinckrodt in disregard for the rights of Local 322 and the harm she caused Local 322 and similarly situated TPPs.

694. Not only was Pratta unjustly enriched by her willful misconduct on behalf of Mallinckrodt, Pratta was also unjustly enriched when the United States Department of Justice settled the qui tam action for $15.4 million—some of which was paid [or will be paid] to Pratta

on top of and in excess of the monies she earned engaging in the same illegal conduct that cause Local 322 harm in this case and which is the subject of this case.

695. By engaging in the unlawful conduct described in this Second Amended Complaint, Pratta knowingly obtained benefits from her illegal and unjust activities.

696. Further, by engaging in said unlawful conduct, Pratta was unjustly enriched by receiving funds from the $15.4 million settlement—funds that could otherwise have been paid to payors like Local 322 but to date were not. Pratta was unjustly enriched by her conduct to the detriment of Local 322 and the Class.

697. The amounts paid by Local 322 and the Class of TPPs were valuable to all Defendants as all Defendants were unjustly enriched by such direct payments, in that, the reimbursement rates charged by Defendants at extremely high prices with inequitable discounts were valuable and beneficial to all Defendants.

698. By engaging in the conduct described herein, Defendants have knowingly obtained benefits from Local 322 and the Class, namely, grossly inflated revenue from their direct involvement in coordinating all aspects of Local 322's and the Class' receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Defendants to retain such benefits.

699. By engaging in the unlawful conduct described herein, Defendants have been knowingly enriched by the amount charged for Acthar over and above what it could have charged in a competitive market, wherein Cigna/Express Scripts would have used its market power to extract lower prices from Mallinckrodt in fulfillment of its obligation to contain costs, and what it could have charged if it had engaged in appropriate cost containment measures.

700. Mallinckrodt, by working with Cigna/Express Scripts in maintaining and

enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade, and engaging in other unlawful acts and practices, Mallinckrodt was able to extract exorbitant revenue from Local 322 beyond what it could have received in the absence of such unlawful conduct. This conduct violated state consumer fraud and antitrust laws, as well as the common law of New Jersey, and, as such, interfered with the legally protected interests of Local 322.

701. Local 322 is therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey demands that judgment be entered in its favor and against all Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

PRAYER FOR RELIEF

WHEREFORE, United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey requests the Court to enter the following relief:

a. Declare unlawful the acts and practices alleged herein, enjoin the Defendants from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;

b. Enter judgment against Defendants for the violations alleged herein;

c. Award the actual damages incurred by Plaintiff as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;

d. Award statutory damages set forth herein under the statutory claims alleged;

e. Award treble damages or multiple damages by operation of law;

f. Award punitive damages;

g. Award Plaintiff the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and

h. Award such other and further relief as the Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury of all issues so triable in this cause.

Respectfully submitted,

United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey

By: /s/Donald E. Haviland, Jr.

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